Effective Health Care Program

Future Research Needs Paper
Number 30

Outpatient Case Management for Adults With Medical Illnesses and Complex Care Needs: Future Research Needs

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Outpatient Case Management for Adults With Medical Illnesses and Complex Care Needs: Future Research Needs

Identification of Future Research Needs From Comparative Effectiveness Review No. 99

Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
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This report is based on research conducted by the Oregon Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2007-10057-I). The findings and conclusions in this document are those of the author(s), who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

The information in this report is intended to help health care researchers and funders of research make well-informed decisions in designing and funding research and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of scientific judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical research and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances.

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None of the investigators have any affiliation or financial involvement that conflicts with the material presented in this report.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

An important part of evidence reports is not only to synthesize the evidence, but also to identify the research needs in evidence that limited the ability to answer the systematic review questions. AHRQ supports EPCs to work with various stakeholders to identify and prioritize the future research that is needed by decisionmakers. This information is provided for researchers and funders of research in these Future Research Needs papers. These papers are made available for public comment and use and may be revised.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality. The evidence reports undergo public comment prior to their release as a final report.

We welcome comments on this Future Research Needs document. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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The EPC sought stakeholder input on the priority areas for research. Stakeholders are not involved in the analysis or the writing of this report. Therefore, in the end, research priorities, research questions, methodological approaches, study design considerations, and/or conclusions do not necessarily represent the views of individual stakeholders.

Stakeholders must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The Task Order Officer and the EPC work to balance, manage, or mitigate any conflicts of interest.

The list of stakeholders who participated in developing this report follows:

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Contents

Tables

Figures

Appendixes

Executive Summary

Background

In 2010, the Agency for Healthcare Research and Quality (AHRQ) charged the Oregon Evidence-based Practice Center with conducting a Comparative Effectiveness Review (CER)[1] to assess the effectiveness of outpatient case management as an intervention strategy for chronic illness management.

The Key Questions the review addressed were:

Key Question 1. In adults with chronic medical illness and complex care needs, is case management effective in improving:

1a. Patient-centered outcomes, including mortality, quality of life, disease-specific health outcomes, avoidance of nursing home placement, and patient satisfaction with care?

1b. Quality of care, as indicated by disease-specific process measures, receipt of recommended health care services, adherence to therapy, missed appointments, patient self-management, and changes in health behavior?

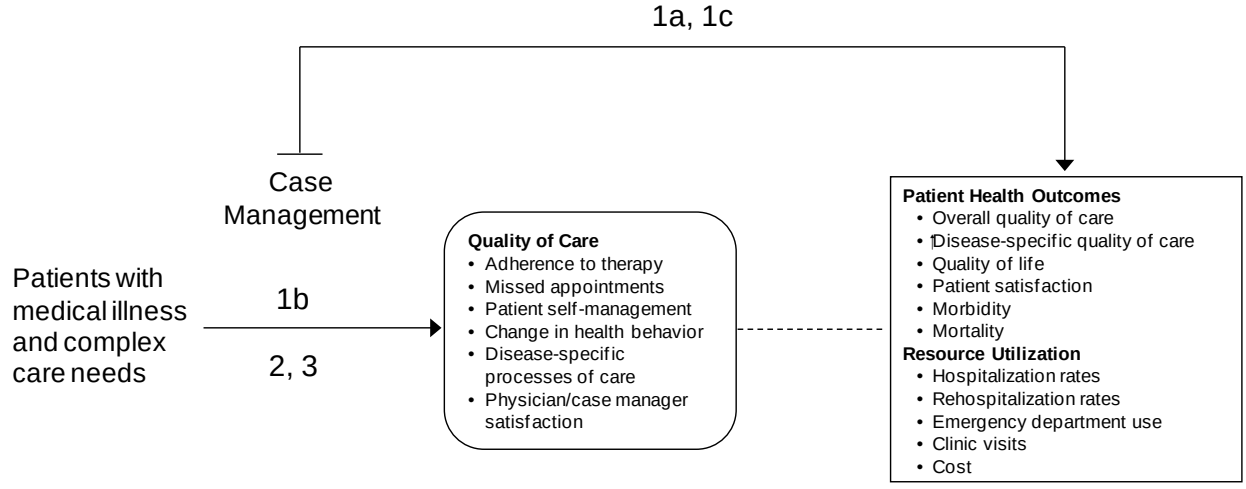
1c. Resource utilization, including overall financial cost, hospitalization rates, days in the hospital, emergency department use, and number of clinic visits (including primary care and other provider visits)?

Key Question 2. Does the effectiveness of case management differ according to *patient characteristics*, including but not limited to: particular medical conditions, number or type of comorbidities, patient age and socioeconomic status, social support, and/or level of formally assessed health risk?

Key Question 3. Does the effectiveness of case management differ according to *intervention characteristics*, including but not limited to: practice or health care system setting; case manager experience, training, or skills; case management intensity, duration, and integration with other care providers; and the specific functions performed by case managers?

The analytic framework (Figure A) outlines the targeted population, interventions, and outcomes for the review.

Figure A. Original analytic framework from Comparative Effectiveness Review



Note: Numbers refer to Key Questions.

After synthesizing the results from 109 studies, the CER concluded that case management (CM) interventions matching the review's definition and scope had limited impact on patient-centered outcomes, quality of care, and resource utilization among patients with chronic medical illness. The review did identify some clinical settings in which CM had positive (though modest) effects on these outcomes.

The CER also identified both limitations of existing studies and gaps in the literature. Based on these, the CER underscores how these limitations and gaps restrict the ability of the existing research literature to answer important questions about CM.

The limitations are related to a fundamental challenge the CER faced—the multiplicity of roles and the variability of day-to-day activities in different CM interventions. This lack of specification made it difficult to: (1) isolate components of CM that might contribute to its effectiveness and (2) be confident that indirect comparisons across studies are comparing equivalent interventions.

The research gaps identified in the CER are summarized below and are organized according to the most relevant element of the PICOT (population, intervention, comparator, outcome, and timing) framework. Contextual issues noted in the CER are included as well.

Population

- Studies that assess the use of risk assessment tools for choosing candidates and determining which patient subgroups achieve the greatest benefits from CM.
- Better specification of populations receiving CM.

Intervention

- Studies to assess the intensity of CM including whether the frequency of CM contacts, length and content of contacts, and approaches to followup of problems have an effect on patient outcomes.
- Studies to determine when CM should emphasize direct support compared with patient education.
- Better specification of the components of CM interventions.

Comparator

- Studies to determine the effectiveness of CM delivered by different case managers.
- Studies to assess the potential to standardize CM and the importance of choosing individuals to implement CM.
- Studies that compare CM to other interventions designed to achieve similar outcomes.

Outcome

- None noted.

Timing

- Studies needed to determine the appropriate length of time for patients to receive CM in order to achieve the best outcomes.

Contextual Issues

- Understanding of specific areas that should be explicit in reporting the characteristic of case managers and the specifics of the CM intervention, including training received by case managers, case manager experience, specific functions of case managers and the distribution of effort devoted to different activities, modes of contact (e.g., clinic visits, home visits, and telephone calls), average caseload, relationship to other health care providers, and the use of protocols, guidelines, and information technology.

There is a relationship between the limitations of the literature and the evidence gaps. Because CM is often poorly defined and sufficient details about the patient population and the intervention are often not provided, current research evidence cannot answer questions about how to best target CM interventions. That is, which patients are most likely to benefit from specific components of CM is not clear.

Methods

To develop an agenda for future research, we began with the limitations and gaps identified in the CER report. We reviewed summaries of the topic refinement and technical expert panel discussions that informed the CER. The lead author of the original report was also a member of the Future Research Needs (FRN) project team. Based on these sources we developed a preliminary list of topics and discussion points.

We presented the CER results and the preliminary list to stakeholders via Webinars and phone discussions and asked them to provide feedback. Using this list the research team created an online questionnaire using SurveyMonkey®. We asked stakeholders to rate the importance of each proposed topic for future research on a scale of 1 to 6 with 1 indicating lowest priority and 6 indicating highest. Stakeholders were instructed to consider the Effective Health Care (EHC) program priorities of importance, desirability of new research, feasibility, and potential impact while ranking each evidence gap topic. We also used open-ended questions to ask stakeholders how future research on CM should be different from research conducted to date, which components of CM interventions should be reported in all studies, and what a standardized definition of CM should include.

We calculated the means of the stakeholder ratings of the topics, and the 15 with the highest overall mean rating were classified as the top-tier research gaps. Responses to the open-ended question answered by all but one of the stakeholders were coded by two team members separately who then reconciled differences and developed the final coding of the responses.

In addition to the stakeholder input, we also searched for ongoing research and recently completed studies. Using the original search strategies for the CER, a research librarian conducted searches of MEDLINE, the Cochrane Central Registry of Controlled Trials, the Cochrane Database of Reviews of Effects, and the Cochrane Database of Systematic Reviews for the time period August 2011-June 2012. Unpublished materials were identified by searching clinical trial registries (ClinicalTrials.gov, Current Controlled Trials, Clinical Trial Results, World Health Organization [WHO] Trial Registries) and governmental grant databases (NIHRePORTER, HSRProj, and AHRQ GOLD), as well as a U.S. private and community foundations database. Full text articles were retrieved if the studies related to the CER Key Questions or if the study appeared to address gaps identified in the review or by the stakeholders. Studies retained after full-text review were then matched with stakeholder identified research

priorities. Finally, for the top-tier FRNs that stakeholders prioritized, we identified potential research designs based on input from the stakeholders.

Results

Nine of 21 invited stakeholders participated in one of two Webinars or a telephone interview and in prioritizing topics. Each stakeholder signed conflict of interest forms and none indicated any conflicts that would preclude them from taking part in the project.

The research team invited stakeholders to participate based on their perspectives. The stakeholders consisted of the following team-identified perspectives: two clinicians/researchers; one research funder; three policy makers, two patient advocates, and one representative of social work/social services. Because stakeholders often bring several perspectives to a task, we asked them to self report their primary perspective. Four of the nine self-identified perspectives matched those assigned by the research team. One stakeholder was invited as a policymaker but self-identified as a researcher; the remaining four opted for the "other" category and provided a category not specifically defined in the recruitment process.

Based on stakeholder input and review of the CER, we generated a list of 61 potential topics for future research. The stakeholder ratings for each topic were evaluated, and there was a distinct separation in the rankings based on both the means and distributions of ratings. Top-tier topics were defined as those with a mean over 4.5 (maximum possible was 6 and the minimum was 1). These top-tier research topics that address current research gaps are relatively specific and fall into five domains in five areas: (A) *global* issues related to definitions and standardization in research; (B) details related to the *implementation of CM*; (C) optimal *patient selection or targeting*; (D) *evaluating components* of complex CM interventions; and (E) *research design* considerations. Table A presents the means and number of stakeholders who gave the topic a high rating and organizes the specific topics by these domains.

Table A. Top-tier research gaps according to stakeholder ratings

Domain	Mean Score	High Priority: Ranked 5-6 % (n)
A. Global		
A1. Establish clear definitions of specific models of CM based, for example, on their components, intensity and duration.	5.67	100% (9)
A2. Establish pragmatic standards for measuring and reporting CM characteristics and outcomes that should be routinely reported in journal articles/study protocols about CM.	5.22	78% (7)
A3. Discuss pragmatic standards for measuring and reporting relevant outcomes, such as utilization, all stakeholders' costs, quality of care, quality of life, and satisfaction.	5.11	67% (6)
B. Implementation of CM		
B1.Describe how CM can be made more efficient so that it is either cost neutral or generates savings.	5.11	78% (7)
B2. Compare CM programs that include access to utilization data and the ability to follow patients across settings and episodes with CM that is limited to specific settings or time periods.	5	78% (7)
B3. Determine the modes of case manager contact (e.g., telehealth, telephone, in-person, home visits, in physician's office, etc.) that are most effective.	4.78	67% (6)
B4. Compare the impact of differences in training/education of case managers.	4.56	56% (5)
C. Patient Selection/Targeting		
C1. Describe the characteristics of patients in CM programs that result in positive outcomes (benefits for patients or positive changes in utilization).	4.89	78% (7)
C2. Examine the impact of tailoring CM activities based on patient characteristics.	4.75	75% (6)
C3. Determine the effectiveness of aligning CM onset, intensity, composition, and duration with the patient's needs.	4.67	67% (6)
D. Evaluation of CM Components		
D1. Examine the role of evaluating the appropriateness of prescribed medications (using existing medication evaluation tools or involving a pharmacist) as part of CM (not simply evaluating adherence).	4.78	67% (6)
D2. Examine the role of including transitional care tools or models as part of CM.	4.78	56% (5)
D3. Examine the link between specific components of CM and specific outcomes (e.g., coordination of care and hospitalization; patient coaching and adherence).	4.56	56% (5)
E. Research Design		
E1. Describe longitudinal evaluation of the impact of CM, particularly for those with chronic illnesses and near the end of life.	4.89	78% (7)
E2. Exposition of the pros and cons of various study designs that would be most productive at this stage (e.g., randomized, cluster-randomized, observational, community trials, and qualitative).	4.78	67% (6)

CM = case management

The searches of bibliographic databases produced 1,219 citations including 949 abstracts of articles reporting ongoing and recently published research, 141 descriptions from clinical trial registries, and 129 project descriptions from grant databases. Of these, we identified 10 studies published after the CER search period and 12 ongoing studies or projects that either had published protocols or were listed in a trials registry. The recently completed studies were published in 2011 or 2012. Eight of them address one or more of the issues/topics prioritized by the stakeholders for future research while two met inclusion criteria for the CER but did not match up with any of the top-tier evidence gaps. The twelve ongoing studies have a range of anticipated end dates from 2012 to 2015. We were unable to determine when two studies were expected to be completed.

The recently completed and ongoing studies addressed at least some component of nine of the top-tier research topics. Three recent studies and one ongoing project correspond to establishing clear definitions of specific models of CM. Four completed and two ongoing studies address how CM can be made more cost efficient. Two recently completed studies focus on determining the modes of case manager contact that are most effective. Two ongoing projects compare the impact of differences in case manager training. Three ongoing studies examine the impact of tailoring CM activities based on patent characteristics. Two recently completed studies and one ongoing study examine the role of evaluating appropriateness of prescribed medication. The same two recently completed studies examine the role of including transitional care models as part of CM. Finally, five completed and four ongoing studies examine the link between specific components of CM and outcomes.

During the Webinars the CER author and stakeholders discussed the idea that future research should focus on developing new clinical paradigms. For this reason, we propose study designs that may help "unpack" the "black box" of CM interventions. In addition to randomized trials and observational studies, we propose research designs of descriptive studies including surveys, expert consensus, program case studies, and practice/policy analysis. Finally, the proposed research agenda includes subgroup analysis and the collection of sufficient information about the intervention when researchers conduct trials or observational studies. For more detail on identified recent and ongoing studies and proposed study designs, please see the full report.

Discussion

The CER concludes and stakeholders agreed that studies that (1) compare CM with usual care and (2) fail to specify, much less test, components of the intervention will not address the outstanding, important questions about CM. This project identified five domains and 15 specific topics for future research that would contribute to answering these questions about CM. Efforts and initiatives that focus on implementation of care delivery models, ongoing quality improvement, and supporting systems of care (e.g., the learning health care organization and frameworks for implementation) may provide perspectives that could inform future research.

There are limitations to our report. Though we attempted to engage stakeholders from a variety of perspectives, the small number of stakeholders involved makes it impossible to include the diversity of perspectives we know exist. Within stakeholder categories that were represented, there are likely to be differences in priorities and opinions that cannot be represented by one person. An additional limitation is that that our literature scan covered only the period after the CER search meaning that we did not identify studies that would have been excluded from the CER for reasons such as study design but which may address some of the specific topics prioritized by the stakeholders.

Conclusions

Based on the finding of the CER and stakeholder input, we identified 15 specific topics for future research that fit into five domains:

- *Global* issues related to definitions and standardization in research
- Details related to the *implementation of CM*
- Optimal *patient selection or targeting*
- Evaluating *components* of complex CM interventions
- *Research design* considerations

Recently published studies or ongoing projects were identified that corresponded to over half of the specific topics, but this body of research is unlikely to resolve the outstanding questions about CM. Rather this list suggests a future research agenda that differs significantly from research completed to date and suggests that future studies should focus on these more specific topics identified during the course of this project rather than repeating general assessments of CM.

References

1. Hickam DH, Weiss JW, Guise J-M, et al. Outpatient Case Management for Adults with Medical Illness and Complex Care Needs. Comparative Effectiveness Review No. 99. (Prepared by the Oregon Evidence-based Practice Center under Contract No. 290-2007-10057-I.) AHRQ Publication No. 13-EHC031-EF. Rockville, MD: Agency for Healthcare Research and Quality. January 2013. www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Background

Chronic diseases affect almost half of the United States (U.S.) population and are a leading cause of illness, disability, and mortality,[1] accounting for 7 out of 10 deaths among American adults.[2] People with chronic diseases often require costly medical interventions and must interact with multiple health care providers. This is particularly the case when patients have more than one chronic condition or a complex condition that requires complex multiple treatments. Often the treatments and services needed are not integrated into a coherent system of care. This fragmentation increases the risk of errors, low quality care, and dissatisfaction and frustration among clinicians as well as patients and their families.[3]

Case management (CM) is clinical strategy that is intended to compensate for this lack of integration of health care services. The core of CM is supplemental coordination. A case manager is usually a nurse or social worker who takes responsibility for coordinating and implementing a patient's care plan, either alone or in conjunction with a team of health professionals. CM tasks include helping patients navigate health care systems, connecting them with community resources, and assisting with administrative and logistical tasks. Case managers also can perform clinical functions, including disease-oriented assessment and monitoring, medication adjustment, health education, and self-care instructions. These additional coordination or clinical functions are often part of other chronic illness management interventions such as interdisciplinary teams, integrated acute and long-term care, or home-based primary care. Because of the broad range of activities that a case manager can perform, the term CM has been used to describe a wide variety of different types of clinical program. This has led to confusion about the usefulness of CM as a clinical intervention.

In 2010, the Agency for Healthcare Research and Quality (AHRQ) charged the Oregon Evidence-based Practice Center (EPC) with conducting a review to evaluate the comparative effectiveness of outpatient CM as an intervention strategy for chronic illness management. The aims of the review were to assess the evidence pertaining to the effectiveness of CM in improving patient-centered outcomes, quality of care, and resource utilization in adults with chronic medical illness and complex care needs. It also evaluated the effectiveness of CM based on patient and intervention characteristics.

In order for the original Comparative Effectiveness Review (CER) to identify and synthesize the available evidence, the scope of the review was limited to carefully defined clinical populations and CM models.

While CM is often used to improve the management of psychiatric illnesses such as depression, schizophrenia, or substance use disorders, the content of CM services for these conditions is substantively different from the CM services provided for chronic medical illness. For this reason the review was restricted to studies about CM interventions for medical illness, as opposed to psychiatric conditions. The review did include studies in which CM was used to improve chronic medical illness care among patients who also had psychiatric illness and CM that integrated care for psychiatric disorders associated with significant medical comorbidities such as dementia. The review was further restricted to CM programs having an ongoing and sustained relationship between the case manager and patient and was limited to CM conducted in outpatient settings. Thus, it did not address short-term CM programs that focus on the transition between inpatient and outpatient settings of care.

The Key Questions the review[4] addressed were:

Key Question 1. In adults with chronic medical illness and complex care needs, is case management effective in improving:

1a. Patient-centered outcomes, including mortality, quality of life, disease-specific health outcomes, avoidance of nursing home placement, and patient satisfaction with care?

1b. Quality of care, as indicated by disease-specific process measures, receipt of recommended health care services, adherence to therapy, missed appointments, patient self-management, and changes in health behavior?

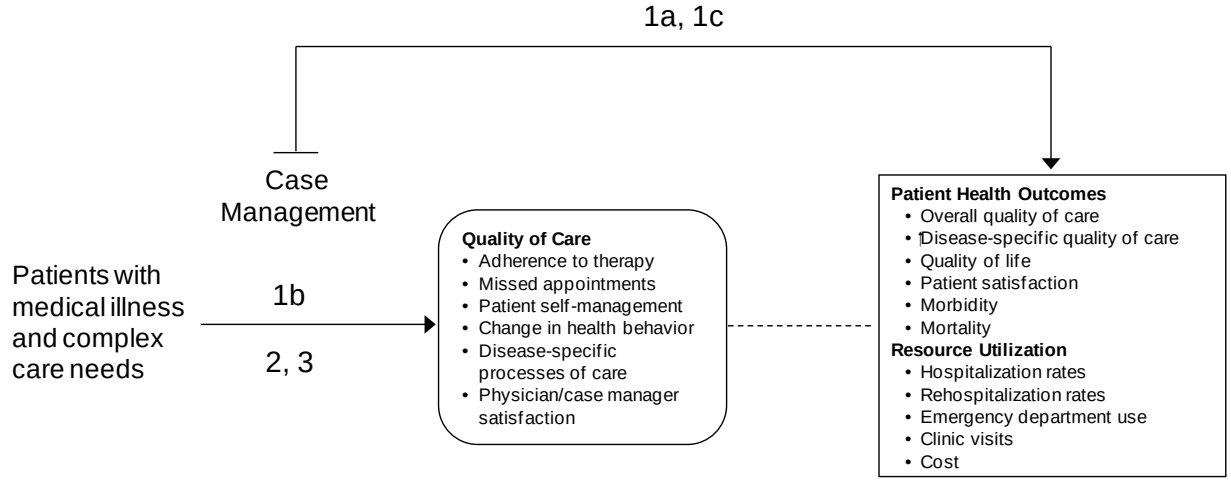
1c. Resource utilization, including overall financial cost, hospitalization rates, days in the hospital, emergency department use, and number of clinic visits (including primary care and other provider visits)?

Key Question 2. Does the effectiveness of case management differ according to *patient characteristics*, including but not limited to: particular medical conditions, number or type of comorbidities, patient age and socioeconomic status, social support, and/or level of formally assessed health risk?

Key Question 3. Does the effectiveness of case management differ according to *intervention characteristics*, including but not limited to: practice or health care system setting; case manager experience, training, or skills; case management intensity, duration, and integration with other care providers; and the specific functions performed by case managers?

The analytic framework (Figure 1) developed for the CER depicts the relationships among the Key Questions and outlines the targeted population, interventions, and outcomes that were the focus of the review.

Figure 1. Original analytic framework from Comparative Effectiveness Review



Note: Numbers refer to Key Questions.

After synthesizing the results from 109 studies, the original CER concluded that, while there were a number of approaches to CM matching the review's definition and scope, the interventions had limited impact on patient-centered outcomes, quality of care, and resource utilization among patients with chronic medical illness. Nevertheless, the review was able to identify some clinical settings in which CM had positive (though modest) effects on these outcomes.

The objective of this Future Research Needs (FRN) project was to engage a range of stakeholders and combine their insight with the results of the CER and a scan of the recent

literature and studies in progress. Drawing from all these sources we sought to identify and prioritize topics for future research that could inform health care decisionmaking and policy regarding CM.

Evidence Gaps

The CER identified a number of limitations in the existing literature and research gaps. Two key limitations are described below. These are followed by important topics not found in the literature, research gaps organized according to the most relevant element of the population, intervention, comparator, outcome, timing, and setting (PICOTS) framework.

The CER also identified both limitations of existing studies and gaps in the literature. Based on these, the CER underscores how these limitations and gaps restrict the ability of the existing research literature to answer important questions about CM.

The limitations are related to a fundamental challenge the CER faced—the multiplicity of roles and the variability of day-to-day activities in different CM interventions make it difficult for evaluations of CM to specify fully the content of the intervention. This lack of specification makes it difficult to: (1) isolate components of CM that might contribute to its effectiveness and (2) be sure that indirect comparisons across studies are comparing equivalent interventions.

Past studies of CM have had methodological limitations that hinder the capability to perform comparisons of alternative models of CM. Few organizations have had the potential scope (in terms of patient base and clinical resources) to conduct evaluations that directly compare different CM approaches. Thus, nearly all research studies have compared a customized CM program to "usual care," in which patients receive no CM services. Another limitation of the evidence base is that most of the individual clinical trials of CM have had small to moderate sample sizes (less than 500 participants per intervention arm). With these numbers it was often not possible to analyze patient subgroups, and many of the trials did not report results by subgroup. For this reason it has not been easy to determine whether CM is more effective for some subgroups of patients than for others.

Key Research Gaps

Population

- Studies that assess the use of risk assessment tools for choosing candidates and determining which patient subgroups achieve the greatest benefits from CM.
- Better specification of populations receiving CM.

Intervention

- Studies to assess the intensity of CM including whether frequency of CM contact, length and content of contacts, and approaches to followup of problems have an effect on patient outcomes.
- Studies to determine when CM should emphasize direct support compared with patient education.
- Better specification of the components of CM interventions.

Comparator	• Studies to determine the effectiveness of CM delivered by different case managers. • Studies to assess the potential to standardize CM and the importance of choosing individuals to implement CM. • Studies that compare CM to other interventions designed to achieve similar outcomes.
Outcome	• None noted.
Timing	• Studies needed to determine the appropriate length of time for patients to receive CM in order to achieve the best outcomes.
Contextual Issues	• Understanding of specific areas that should be explicit in reporting the characteristic of case managers and the specifics of the CM intervention, including training received by case managers, case manager experience, specific functions of case managers and the distribution of effort devoted to different activities, modes of contact (e.g., clinic visits, home visits, and telephone calls), average caseload, relationship to other health care providers, and the use of protocols, guidelines, and information technology.

There is a relationship between the limitations of the literature and the evidence gaps. Because CM is often poorly defined and sufficient details about the patient population and the intervention are often not provided, current research evidence cannot answer questions about how to best target CM interventions. That is, which patients are most likely to benefit from specific components of CM is not clear.

Methods

This project involved two main activities: stakeholder engagement and a literature scan. These activities expanded on the FRNs identified by the authors of the CER. Stakeholders were engaged to develop a detailed list of relevant topics for future research and then to prioritize these topics. A literature scan was used to identify studies completed since the CER was completed as well as ongoing research and initiatives related to gaps in the evidence base.

The protocol and goals for this project were reviewed by the Institutional Review Board (IRB) at Oregon Health & Science University. The IRB determined that this project did not meet the definition of human subject research per 45 CFR 46.102(f) (IRB #: IRB00008449).

Identification of Evidence Gaps

We began with the evidence gaps described in the CER report. Next, the project team reviewed summaries of the topic refinement and technical expert panel discussions that informed the CER. We also received input from the lead author of the original report, who was a member of the FRNs project team. From these sources we developed a preliminary list of topics and discussion points to pursue with the stakeholders. Finally, additional evidence gaps and potential research topics were generated by stakeholders during two Webinars and one individual interview. The project team worked together to organize all the evidence gaps into unique topics or questions and to categorize these according to the PICOTS framework. Stakeholders then provided additional feedback on the categorized topics list.

Topics considered relevant for this FRN project included those that fit within the scope of the original CER. Also considered relevant were topics raised during the planning and execution of the CER, including topics related to the identification and synthesis of evidence on the effectiveness of CM (such as efforts to establish definitions of models of CM).

Engagement of Stakeholders

Identifying and Recruiting Stakeholders

In order to have a variety of input, the team identified and recruited stakeholders from different perspectives. These stakeholders included clinicians, researchers, research funders, policymakers, and patient advocates. Our main priority was to have at least one representative from each stakeholder category so that the discussion and prioritization of research gaps incorporated multiple stakeholder perspectives.

Recruitment occurred during May and June 2012. We sought to create a group that could interact and collectively provide an assessment of the research needed to advance health policy and practice related to CM.

The research team sent written invitations to the potential stakeholders/participants (see Appendix A). The letters included a brief overview of the project, explained what participation would entail, and provided contact information in case there were any questions. Followup emails were sent as needed, and reminder phone calls were made in some cases. In compliance with Federal guidelines we did not aim to recruit more than nine non Federal employees. Participation at all stages was voluntary, and participants were free to decline to participate in any activity or decline to answer any specific question.

Once individual stakeholders agreed to participate, a member of the research team contacted them with further details. Stakeholders were offered the choice of two dates to attend a Webinar.

Accommodations for individual phone calls were made in the case that interested stakeholders could not attend either of the Webinars.

Disclosure and Evaluation of Conflicts of Interest

All participating stakeholders received the "EPC Conflict of Interest Disclosure Form." All stakeholders completed and returned the disclosure before participating in Webinars or interviews. The research team and the Agency for Healthcare Research and Quality (AHRQ) Task Order Officer reviewed disclosures from the stakeholders who agreed to participate and did not identify any financial or professional/business conflicts that would preclude any of the stakeholders from participating in the project.

Stakeholder Engagement

The research team hosted two Webinars on different days and times in order to accommodate stakeholder schedules. Materials were sent to all stakeholders before the scheduled Webinars. These materials included the draft executive summary of the CER, the protocol for this FRN project, instructions for accessing Adobe® Connect™, and a copy of the PowerPoint® slides to be used for the Webinars. The research team, including the principal investigator of the CER, hosted the Webinars via Adobe Connect. Audio recordings were made after the participants provided verbal permission to record the discussions.

There were three main aims of the Webinars: (1) to provide an overview of the CER; (2) to provide further explanation of the FRNs project goals, introduce the Effective Health Care (EHC) Program, and answer any stakeholder questions; and (3) to engage stakeholders to identify research needs and augment the gaps identified in the CER. Each Webinar lasted approximately 90 minutes and consisted of approximately the same content, though the discussion varied somewhat according to the expertise and interests of the participants at the two sessions. The Webinars were facilitated by one investigator, with each investigator presenting a portion of the background material, answering stakeholder questions, and asking followup questions of the stakeholders as needed to clarify topics they suggested.

At the end of each Webinar, we informed stakeholders that they could contact us with any further comments or questions if they desired. We informed them that we would contact them shortly with a list of research gap topics for their review and revision so that they could provide comments and additions before we created the online questionnaire. Because one stakeholder could not attend either Webinar, we scheduled an individual telephone call, during which we presented the same information reviewed in the Webinars and solicited feedback.

The audio portion of the Webinars and telephone call were professionally transcribed. Team members reviewed the transcripts to make sure that all stakeholder input was considered and all topics identified during the discussion were included in the draft list. We then created a list of research gaps that included those listed in the CER as well as those generated through the Webinars. Prior to creating the questionnaire used to rank the topics, all stakeholders received the list of potential topics and were asked to submit any amendments or additions. Some replied with additions which were included in the questionnaire.

Prioritization

Using the list of topics for evidence gaps developed with the stakeholders, the research team created an online questionnaire (see Appendix B) using SurveyMonkey®. To assess

comprehensiveness and usability we piloted the instrument with a small convenience sample of five individuals. We incorporated suggestions from pilot participants before sending the final link to stakeholders. Each stakeholder who participated in the Webinars or telephone interview was invited to respond to the questionnaire. Reminders were sent via email as necessary.

The questionnaire consisted of three parts. In the first section respondents were asked to self-identify their perspective and were provided instructions for the questionnaire. Stakeholders were instructed that throughout the questionnaire they should keep in mind the EHC program priorities of importance, desirability of new research, feasibility, and potential impact while ranking each evidence gap topic. The second section listed 61 topics identified as potential research gaps. For presentation purposes, we grouped topics together by the PICOTS that they best addressed as well as an "other" section for those that did not fall into a particular PICOTS category. Stakeholders were asked to rate the priority of each gap for future research on a scale of 1 to 6, with 1 indicating lowest priority and 6 indicating highest priority. Respondents also could provide additional text comments at the end of each section. The final section consisted of open-ended questions where stakeholders were asked how future research on CM should be different from current and previous research, which components of CM interventions should be reported in all studies, what a standardized definition of CM should include, and a request for information about any related ongoing or recently published studies.

Analysis

From the priority ratings selected by each respondent, mean values for each topic were computed. The topics were then sorted by the mean rating to identify the top tier of evidence gaps. The distribution of the responses was also reviewed, that is the number of times they appeared in the highest, middle, and lowest priorities (rated 5-6, 3-4, and 1-2, respectively). Because there was a clear break at 15 items and these 15 corresponded to a small number of domains, we did not engage in a second round of prioritization. For the open-ended responses, we used a thematic analysis method to group these into categories.

Identification of Recently Completed and Ongoing Studies

A research librarian conducted searches to identify research funding, ongoing research, and recently completed research. The original search strategies used for the CER were repeated for the time period August 2011-June 2012. Searches were conducted using MEDLINE, the Cochrane Central Registry of Controlled Trials (CCRCT), the Cochrane Database of Reviews of Effects (DARE), and the Cochrane Database of Systematic Reviews. Unpublished materials were identified by searching clinical trial registries (ClinicalTrials.gov, Current Controlled Trials, Clinical Trial Results, World Health Organization [WHO] Trial Registries) and governmental grant databases (NIHRePORTER, HSRProj, and AHRQ GOLD), as well as a U.S. private and community foundations database (for detailed search strategy see Appendix C). Titles and abstracts were triaged by two team members, with full-text pulled and reviewed if at least one team member thought the study might be related to the CER Key Questions or if the study appeared to address information gaps identified in the review or by the stakeholders. Studies retained after full-text review were then matched with stakeholder identified research priorities.

Research Question Development and Research Design Considerations

For the top-tier FRNs we identified specific questions and research designs based on input from the stakeholders. At several points stakeholders stated that multiple approaches or types of research were needed in order to provide answers that were not available from previous research. Additional factors in proposing research designs to be considered included: the feasibility of the design; the resources required; ethical considerations, particularly in terms of what can be used as a comparator; and the relevance to future implementation in health services delivery and policy.

Results

Recruitment and Participation

Nine of 21 invited stakeholders participated in the project. Out of the stakeholders we contacted, the Webinars and a phone interview included two of the six clinicians/researchers (33 percent); one of the five research funders (20 percent); three of the five policymakers (60 percent); two of the three patient advocates (67 percent); and one of the two representing social work/social services (50 percent) (See Table 1).

Of the nine stakeholders, three participated in the first Webinar and five participated in the second Webinar held about a week later. Stakeholders who participated in the first Webinar included one research funder, one clinician/researcher, and one health policymaker. The second Webinar included one clinician/researcher, one patient advocate, one stakeholder from social work/social services and two health policymakers. One stakeholder, a patient advocate, was interviewed separately due to scheduling conflicts. The second Webinar was also used as an opportunity for mentoring as two junior colleagues of a stakeholder attended.

After the completion of both Webinars and the phone conference, stakeholders were asked to respond first to a followup email and then complete an online questionnaire. Stakeholders often have numerous roles and bring several perspectives to a task based on prior as well as current experience, so we asked stakeholders to self report their primary perspective. Their self-reported perspectives as well as the perspective assigned by the research team at recruitment are reported in Table 2. Four of the nine self-identified perspectives matched up with that assigned by the research team. One stakeholder was invited as a policymaker but self-identified as a researcher; the remaining four opted for the "other" category and provided a category not specifically defined in the recruitment process.

Table 1. Stakeholders who agreed to participate

Stakeholder Perspective (Assigned by Project Team)	Total Invited	Agreed	Participation Rate	Invited Organizations and Individuals
Clinical/Research	6	2	33%	New Courtland Center for Transitions and Health, University of Pennsylvania; Indiana University; Department of Geriatric Medicine University of Oklahoma; NYU Langone Medical Center; Johns Hopkins Bloomberg School of Public Health; Frances Payne Bolton School of Nursing, Case Western Reserve University
Funder	5	1	20%	Veterans Affairs; Center for Delivery, Organization and Markets, Agency for Health Research and Quality; National Institute on Aging; National Institute of Nursing Research; Centers for Medicare & Medicaid Services
Health Policy	5	3	60%	Office of Health Insurance Programs New York State Department of Health; Oregon Health & Science University; Mathematica Policy Research
Social Work/Social Services	2	1	50%	The John A. Hartford Foundation; New York Academy of Medicine, Social Work Leadership Institute
Patient Advocate	3	2	67%	National Council on Aging; AARP; California Health Care Foundation
Total	21	9	43%	

AARP = American Association of Retired Persons; NYU = New York University

Table 2. Perspectives of participating stakeholders

Respondent	Team Perspective Assigned	Self-Reported Perspective
1	Clinical/Research	Researcher
2	Funder	Funder
3	Health Policy	Policymaker
4	Health Policy	Other: Leader interested in system design
5	Clinical/Research	Researcher
6	Health Policy	Researcher
7	Patient Advocate	Other: Multiple roles
8	Social Work/Social Services	Other: Convener of national care coordination coalition
9	Patient Advocate	Other: Organizational Innovation, Capacity and Quality

Identification of Research Gaps

An initial list of potential topics for future research was compiled by project staff and then was sent to the stakeholders for comments, additions, and corrections. The revised list of 61 topics was finalized and used for the remainder of the rating and prioritization process. These items are listed below, organized according to PICOTS with the addition of an "other" category for overarching topics that did not fit into a PICOTS category.

Population

Studies are needed to:

- Describe the characteristics of patients in CM programs that result in positive outcomes (benefits for patients or positive changes in utilization).
- Assess the use of risk assessment tools for choosing patients most likely to benefit from CM.
- Examine CM for patients with multiple comorbidities and issues (i.e., studies that do not exclude patients based on severity, diagnosis, or other aspects of need).
- Examine whether the known risk factors for rehospitalization (e.g., functional status, social support, number of past hospitalizations) would be useful in targeting CM.
- Incorporate large sample sizes (more power), e.g., large observational cohort studies, large trials and/or registries.
- Determine the impact of patient literacy (or the case manager's ability to address patient literacy) on effectiveness of CM.
- Assess the impact of patient activation (a specific measure that includes confidence, engagement, skills and knowledge) on the effectiveness of CM.
- Compare characteristics of patients who choose to participate with those who choose not to participate in CM.
- Compare CM programs that automatically enroll patients with programs where patients have to choose to enroll (i.e., opt-in vs. opt-out programs).
- Describe longitudinal evaluation of the impact of CM, particularly for those with chronic illnesses and near the end of life.
- Determine what strategies are most effective to engage persons in CM who are otherwise disengaged from the health care system.

Intervention

Studies are needed to:

- Assess the impact/importance of the characteristics of the individual serving in the role of case manager (individual traits such as personality, motivation, etc.).
- Evaluate what is the right caseload for case managers.
- Compare the impact of differences in training/education of case managers.
- Compare the impact of case managers from different disciplines (e.g., nurses, social workers, and pharmacists).
- Compare case managers integrated into teams versus case managers working alone.
- Examine the relationship of the case manager with the patients and families and how that relationship impacts outcomes.
- Examine the role of primary care providers in identifying patients who could benefit from CM.
- Assess how to keep case managers focused on the highest-impact components of CM (e.g., supervision and/or incentives).
- Examine the impact of tailoring CM activities based on patient characteristics.
- Compare the effectiveness of standardized CM protocols with more flexible CM protocols.
- Assess whether CM protocols are followed (e.g., fidelity assessments to document whether CM is actually implemented as planned).
- Compare the effectiveness of CM focused on patient education with CM focused on direct patient support activities (e.g., coaching and coordinating care).
- Compare different ways to provide patient education within CM.
- Evaluate the impact of patient-provider interaction techniques or models (e.g., motivational interviewing, coaching, or stages of change) on the effectiveness of CM.
- Examine the link between specific components of CM and specific outcomes (e.g., coordination of care and hospitalization; patient coaching and adherence).
- Examine the role of comprehensive medical management in CM (e.g., ability of case manager to make clinical recommendations or decisions, such as adjusting medications or treatments).
- Examine the role of evaluating the appropriateness of prescribed medications (using existing medication evaluation tools or involving a pharmacist) as part of CM (not simply evaluating adherence).
- Examine the role of including transitional care tools or models as part of CM.
- Compare CM programs that include access to utilization data and the ability to follow patients across settings and episodes with CM that is limited to specific settings or time periods.
- Compare CM programs that vary in intensity.
- Assess potential ways to standardize CM.
- Establish criteria for rating the quality of CM programs (so that quality of CM programs and the effectiveness of programs at different levels of quality can be compared).
- Establish the core components/minimum elements needed for CM.
- Assess the impact of the use of information technology on the effectiveness of CM.
- Examine alternative CM models or new models of care that include CM.

- Compare CM programs with different specific missions or focuses (e.g., focus on preventing major events like hospitalization vs. supporting behavior change).
- Determine the modes of case manager contact (e.g., telehealth, telephone, in-person, home visits, physician's office, etc.) that are most effective.
- Determine the effectiveness of different forms of all of the components of CM (including assessment, evidence-based care planning, patient/family education, engagement/coaching for self-management, coordination of care, proactive monitoring, and integrating with community agencies).
- Determine the effectiveness of aligning CM onset, intensity, composition and duration with the patient's needs.

Comparator

Studies are needed to:

- Compare CM with other non-CM interventions designed to achieve similar outcomes.
- Compare the effectiveness of different CM components rather than compare CM with usual care.

Outcomes

Studies are needed to:

- Determine how CM can be made more efficient so that it is either cost neutral or generates savings.
- Assess which resource utilization is the primary outcome for CM.
- Evaluate the impact of CM on families of patients and whether that impact is related to other outcomes.
- Examine other outcomes of CM, such as whether or not it reduces pressure on other parts of the system (i.e., does it make physician's work easier?).
- Interpret pragmatic standards for measuring and reporting relevant outcomes, such as utilization, all stakeholders' costs, quality of care, quality of life, and satisfaction.

Timing

Studies are needed to:

- Examine whether timing of CM after hospital discharge is associated with effectiveness of CM.
- Evaluate how long patients should be enrolled in CM and what should trigger disenrollment.

Setting

Studies are needed to:

- Examine different settings and organizations for CM (e.g., role of a single person versus part of primary care).
- Assess how CM can be incorporated into Accountable Care Organizations.
- Compare the effectiveness of CM based in different types of organizations (e.g., insurer, non-profit, hospital-based, primary care provider based, and specialist provider based).

- Examine the effects of different payment approaches (e.g., capitation vs. shared savings vs. fee for service).
- Assess effects of CM in high health services utilization versus low-utilization geographic regions.
- Compare CM in integrated systems with CM in organizations that are not part of an integrated system.
- Examine CM in managed care/health plans/non-academic settings.
- Examine the influence of family caregivers on CM outcomes.

Other

Studies are needed to:

- Establish pragmatic standards for measuring and reporting CM characteristics and outcomes that should be routinely reported in journal articles/study protocols about CM.
- Establish clear definitions of specific models of CM based, for example, on their components, intensity, and duration.
- Exposition of the pros and cons of various study designs that would be most productive at this stage (e.g., randomized, cluster-randomized, observational, community trials, and qualitative).

Ranking by Stakeholders

The stakeholder ratings for each topic were summed and divided by the number of respondents to produce a mean score. The mean scores and distributions for all 61 topics are included in Appendix D. There was a distinct separation in the rankings based on both the mean and distributions. Top-tier topics were defined as those with mean over 4.5 (where the maximum possible is 6 and the minimum is 1). Table 3 presents the means and distribution of responses of this top tier of 15 topics.

Table 3. Top-tier research gaps according to stakeholder ratings

Domain	Mean Score	High Priority: Ranked 5-6 % (n)
A. Global		
A1. Establish clear definitions of specific models of CM based, for example, on their components, intensity and duration.	5.67	100% (9)
A2. Establish pragmatic standards for measuring and reporting CM characteristics and outcomes that should be routinely reported in journal articles/study protocols about CM.	5.22	78% (7)
A3. Discuss pragmatic standards for measuring and reporting relevant outcomes, such as utilization, all stakeholders' costs, quality of care, quality of life, and satisfaction.	5.11	67% (6)
B. Implementation of CM		
B1.Describe how CM can be made more efficient so that it is either cost neutral or generates savings.	5.11	78% (7)
B2. Compare CM programs that include access to utilization data and the ability to follow patients across settings and episodes with CM that is limited to specific settings or time periods.	5	78% (7)

Table 3. Top-tier research gaps according to stakeholder ratings (continued)

Domain	Mean Score	High Priority: Ranked 5-6 % (n)
B. Implementation of CM (continued)		
B3. Determine the modes of case manager contact (e.g., telehealth, telephone, in-person, home visits, in physician's office, etc.) that are most effective.	4.78	67% (6)
B4. Compare the impact of differences in training/education of case managers.	4.56	56% (5)
C. Patient Selection/Targeting		
C1. Describe the characteristics of patients in CM programs that result in positive outcomes (benefits for patients or positive changes in utilization).	4.89	78% (7)
C2. Examine the impact of tailoring CM activities based on patient characteristics.	4.75	75% (6)
C3. Determine the effectiveness of aligning CM onset, intensity, composition, and duration with the patient's needs.	4.67	67% (6)
D. Evaluation of CM Components		
D1. Examine the role of evaluating the appropriateness of prescribed medications (using existing medication evaluation tools or involving a pharmacist) as part of CM (not simply evaluating adherence).	4.78	67% (6)
D2. Examine the role of including transitional care tools or models as part of CM.	4.78	56% (5)
D3. Examine the link between specific components of CM and specific outcomes (e.g., coordination of care and hospitalization; patient coaching and adherence).	4.56	56% (5)
E. Research Design		
E1. Describe longitudinal evaluation of the impact of CM, particularly for those with chronic illnesses and near the end of life.	4.89	78% (7)
E2. Exposition of the pros and cons of various study designs that would be most productive at this stage (e.g., randomized, cluster-randomized, observational, community trials, and qualitative).	4.78	67% (6)

CM = case management

These top-tier research topics that would address research gaps were relatively specific and fell into five domains in five areas: (A) *global* issues related to definitions and standardization in research, (B) details related to the *implementation of CM*, (C) optimal *patient selection or targeting*, (D) *evaluating components* of complex CM interventions, and (E) *research design* considerations. The domains and specific topics presented in Table 3 are described in more detail in the following text. This description includes a discussion of the potential study designs for each domain as well as examples of research questions with corresponding possible study designs and PICOT (Tables 4–7). These are meant to be illustrative, not inclusive as several different questions and study designs could correspond to each topic.

Research Topic Domains and Potential Study Designs

A. Global Domain

Both the CER and the discussion among stakeholders identified that a major challenge in synthesizing the available evidence about CM was the lack of clear definitions and standards. Therefore, in order to approach the synthesis of the available evidence on CM, the CER team developed a definition that was applicable to the available research studies, and this was only

partly consistent with definitions developed by other organizations and researchers. With heterogeneity of the CM interventions, it is often hard to be definitive when statements are made about CM based on a synthesis of results across studies of interventions that are believed to be similar (but may actually differ in important ways). Contributing to this lack of clarity is the use of various terms, such as care coordination, care management, disease management, or patient navigation, for interventions that may or may not correspond to CM.

The importance of clarity about the features of CM programs is reflected in the high ranking given to topic A.1 about the need for definitions of CM models. Topics A.2 and A.3 address the need to develop better standards for reporting the applicable research methods in journal publications.

Table 4. Example specification for global domain

Example Research Question	Proposed Study Design	P	I	C	O	T
What are the core components of a CM intervention?	Survey	Organizations with CM programs	CM programs	None	List and ranking of program components	NA

CM = case management; NA = not applicable; PICOT = population, intervention, comparator, outcome, and timing

B. Implementation of Case Management Domain

Related, but more specific than the global topics, is a group of topics that focus on key elements of how CM is implemented in practice. The stakeholders discussed the need to study variations in implementation in order to determine how the effectiveness of CM can be maximized. Stakeholders noted that organizations often are looking for an evidence base that will help them decide how to organize and deliver CM and that the existing research often does not help them answer these questions. The highest priority areas rated by the stakeholders include cost effectiveness (topic B.1), data and access across episodes and settings (topic B.2), modes of CM and patient communication (topic B.3), and the training and education needed for effective case managers (B.4). For these topics the primary research goals would be to determine what variations in CM implementation are most likely to result in positive outcomes.

Table 5. Example specification for implementation domain

Example Research Question	Proposed Study Design	P	I	C	O	T
What mode of case manager-patient contact is most effective?	Observational study	Complex patients	CM with regular in person contact	CM by telephone with in person contact only at intake	Hospitalization, emergency visits	Long-term followup

CM = case management; PICOT = population, intervention, comparator, outcome, and timing

C. Patient Selection/Targeting Domain

A recurring theme in both the CER and the stakeholder discussions was the idea that CM would be more effective if it could be targeted to the patients who need it most and/or tailored to their specific needs. This idea is embodied in three future research topic suggestions that

approach this from different angles. Topic C.1 suggests that future studies be used to identify which subgroups of patients are most likely to benefit from CM. This is an exploratory approach that requires studies with diverse patients and large enough sample sizes to allow valid subgroup analysis. The other topics in this domain propose a different approach. Topic C.2 recommends studying CM interventions in which a variety of distinct services or components are available (e.g., medication management, transition care, functional assessments, caregiver support, and coordination of specialist, etc.) and the CM intervention involves customizing CM by using just the components that match the patients needs. Topic C.3 extends this customization from specific services or components to details of CM implementation. In this case stakeholders suggested the need to better understand when different patients need CM and how much they need as well as what they need. These topics suggest that customization may make CM more efficient. The previous published studies of CM commonly included a step in which case managers performed clinical needs assessments for individual patients, and the perspective of the stakeholders was that this function needs a stronger emphasis in future research.

Table 6. Example specification for targeting domain

Example Research Question(s)	Proposed Study Design(s)	P	I	C	O	T
What is the profile of patients for whom outpatient CM improves outcomes	Trial with risk profiling	Patients enrolled in outpatient CM	Intensive CM	Disease management	Hospitalization, Services utilization, Clinical outcomes for patients stratified by risk profile	Long-term followup of at least 2 years

CM = case management; PICOT = population, intervention, comparator, outcome, and timing

D. Evaluation of Case Management Components Domain

A defining characteristic of CM is that it is a complex, multifaceted intervention. What a case manager does or what is included in a CM intervention includes activities that can be considered separate interventions. An area for future research identified by the stakeholders is to identify the added value obtained by including certain activities in CM. They identified two specific activities, medication assessment (topic D.1) and transitional care (topic D.2), that future research could evaluate as part of CM. The third topic (topic D.3) in this domain is more general in that it proposes that future research should attempt to disaggregate the components of CM interventions that are the subject of study and examine the link between these components and specific outcomes.

Table 7. Example specification for evaluation of case management components domain

Example Research Question	Proposed Study Design	P	I	C	O	T
Is CM with integrated transitional care more effective?	Head-to-head trial	Patients with complex medical needs who initiate case management after a hospitalization	CM with integrated transitional care	CM without transitional care	Readmission to hospital, Hospitalization for any reason, emergency visits	Long-term at least 2 years

CM = case management; PICOT = population, intervention, comparator, outcome, and timing

E. Research Design Domain

The final two proposed and highly ranked topics address specific approaches to study designs. One of the critiques of the current literature is that the followup period in evaluations of CM may not be appropriate, particularly if the CM intervention is designed to manage chronic illnesses or end of life care. Topic E.1 is directly related to this issue and calls for longitudinal studies. Topic E.2 is more general and grew out of the discussion by the stakeholders of the CER results. While the CER reported on a relatively large body of literature, the stakeholders felt that this literature does not answer Key Questions that are important to clinicians, patients, and policymakers. Different research might need to employ a wider variety of methods. For example, it was suggested that a randomized trial that compares patients assigned to CM to others assigned to usual care is unlikely to help answer questions about how best to implement CM. These questions might be answered through case studies or comparisons of practices (clusters) that take different approaches to implementing CM.

This input was used to inform the proposed study designs provided as examples above and in Table 9 below. However, they were also retained as topics for future research because they suggest that methodological research and development is needed to advance the field. While the stakeholders agreed that innovative approaches are needed, the methods needed to answer the questions raised in the other domains are well developed or easily available to researchers.

Responses to Open-Ended Items

The stakeholder questionnaire included optional open-ended items. (The questions and layout are included in Appendix B.) Not all stakeholders provided responses to open-ended items. For this reason they were used to inform this report, but all of these open-ended responses are not reported separately. The one exception is the open-ended item that asked what should be reported and/or measured in all studies of CM. Eight of nine stakeholders provided responses to this question and the stakeholder responses are categorized and listed in Table 8. All the responses we received and how they were coded to construct the categories in the table are included in Appendix E.

It is not surprising that these responses overlap with the domains of the topics proposed for future research. The literature scan also confirmed that these are key topics and are the subject of ongoing research and policy projects (more information is provided in that section below). However, the stakeholders strongly endorse the need for these efforts, and there was agreement that better information in both study protocols and reports is essential to all future research on CM.

Table 8. Stakeholder responses to item about what should be reported and/or measured in all case management studies

Categories of What Should Be Reported/Measured	Stakeholder Responses
Implementation specifics	• Intensity/duration • Termination criteria • Mode of contact • How the contact is made and what is done at each contact
Caseload	• Caseload
Case manager characteristics	• Identification of all members of the team and roles/responsibilities • Background/training of case managers
CM description/components	• Greater specificity of all aspects of the interventions • Approach to education • Care plan details • Medication management • Family caregiver interventions
Environment/context	• Interaction with usual care providers • Implementation process/challenges • How CM fits into the overall design of the clinic • Type and frequency of interactions between and among team members with primary care provider
Cost	• All program costs • The cost outcome • Return on investment
Patient selection/characteristics	• Patient selection criteria • Identification of population targeted for CM
Outcomes: general	• Major system impact of CM • Effects on all stakeholders • Goals
Clinical outcomes	• The clinical outcome
Patient satisfaction	• Patient satisfaction

CM = case management

Literature Scan Results

The searches of bibliographic databases produced 1,219 citations (see search strategies in Appendix C). This included 949 abstracts and articles reporting ongoing and recently published research, 141 descriptions of clinical trials from registries, and 129 project descriptions from grant databases. Most were outside the scope of the original CER or did not address potential topics for future research. After examination of full-text and followup on registry entries we identified 10 studies published after the period covered by the search for the CER and 12 ongoing studies or projects that either had published protocols or were listed in a trials registry.

As the literature scan was conducted at the same time as the stakeholder engagement, the search was broader than the topics identified; however, almost all studies and projects matched the domains if not the exact specific topic.

Recent Studies

Selected information about the recent studies identified in the literature scan is provided in Appendix F. The studies were all published in 2011 or 2012. Eight of the studies[5-12] addressed one or more of the issues/topics prioritized by the stakeholders for future research. Two studies[13, 14] met the inclusion criteria for the CER in that they evaluated the effectiveness of outpatient CM but they did not address any of the identified topics for evidence gaps. The eight studies addressed 9 of the 15 top-tier topics and topics in all the domains except Research Design. The

most common domain for these study topics was the link between specific components of CM and specific outcomes, which was the subject of five studies.[5, 9-12]

While the Research Design domain was not addressed directly in these studies, an examination of the types of studies reveals the frequent use of mixed methods in their study designs. One study was a randomized trial[12] and two studies involve re-examination or supplemental analysis of a previously published randomized trial that was included in the CER.[6, 9] One study used matched controls in a pre-post design,[15] two combined surveys and case studies,[7, 8] one combined observational data with survey data,[10] and one combined case studies with a literature review.[11]

Ongoing Studies

Information about the 12 relevant, ongoing studies is included in Appendix G. These studies were identified via published protocols, entries in trial registries, or descriptions in articles that led to more detailed information. As these are studies in progress, less information is often available than may be available for a completed study. The identified studies and project have a range of anticipated end dates from 2012 to 2015. In some cases we were unable to locate information on when the study was expected to be completed.[16, 17]

The ongoing studies addressed 6 of the 15 top-tier topics included some topics in all domains except Research Design. The most common topics were the link between specific components of CM and specific outcomes, which was the topic of five ongoing studies[17-21] and making CM more efficient or cost effective, which was the focus of three.[20-22]

The ongoing studies contained more randomized trials than the recent studies we identified, but this is likely to be the result of including trial registries in our searches and the fact that registration/reporting of protocols for nonrandomized studies is less common. Six of the 12 ongoing studies were randomized trials including two cluster randomized trials[22, 23] and four in using randomization at the level of individual patients.[18, 24-26] We also identified protocols for two systematic reviews[17, 19] and one prospective cohort study.[21] Three of the studies or projects in progress involved multiple qualitative methods including interviews, focus groups, text analyses, and expert consensus.[16, 20, 27]

Synthesis of Results: Foundation for a Future Research Agenda

This FRN project identified significant and essential questions that remain unanswered. Table 9 combines the domains and specific topics identified by stakeholders, recent studies, and ongoing research and suggested potential study designs.

During the Webinars the CER author and stakeholders discussed the idea that perhaps there already has been enough research on CM based on the currently defined clinical models and that future research should focus on developing new clinical paradigms. Specifically the participants agreed that more research – either trials or observational studies – that compare CM to usual care and treat CM as a single, uniform intervention ("black box") are not needed. Rather, what is needed are studies that (a) compare CM to other care models designed to correct for fragmented care; (b) "unpack" the black box of CM interventions by both specifying what the intervention involves and linking specific components to specific outcomes; and (c) studies that use different research approaches to obtain information about how best to implement CM in practice. The domains, topics, and potential study designs proposed by this FRN project are intended to help

researchers, funders, and other stakeholders focus future efforts. The project results support a research agenda that will give clinicians and policymakers the information they need to decide when CM is an appropriate intervention and how it can be implemented so that it promotes high-quality and cost-effective care.

Table 9. Topics for future research, recent and ongoing studies, and potential study designs

Domain	Specific Top-Tier Topics	Applicable PICOT Gap	Recent Studies	Ongoing Research	Potential Study Designs
A. Global	A.1. Establish clear definitions of specific models of CM based, for example, on their components, intensity and duration.	Other	Hughes, 2011[8] Reilly, 2011[10] Ross, 2011[11]	Morales-Asencio, 2010[16]	Descriptive studies: - Expert consensus. - CM Program Case Studies. - Practice/Policy Analysis. - Surveys.
	A.2. Establish pragmatic standards for measuring and reporting CM characteristics and outcomes that should be routinely reported in journal articles/study protocols about CM.	Other			Descriptive studies: - Expert consensus. - Surveys.
	A.3. Studies with pragmatic standards for measuring and reporting relevant outcomes, such as utilization, all stakeholders' costs, quality of care, quality of life, and satisfaction.	Outcomes			Descriptive studies: - Expert consensus. - Surveys.
B. Implementation of CM	B.1. Studies of how CM can be made more efficient so that it is either cost neutral or generates savings.	Outcomes	Baker, 2011[5] Hines, 2011[7] Peikes, 2012[9] Ross, 2011[11]	King's Fund, 2012[20] Koopmans, 2012[21] Raven, 2012[22]	Trials or observational studies that collect relevant: - Cost and resource utilization data as outcomes. - Sufficient information about the intervention in order to assess the factors that affect efficiency and cost-effectiveness.
	B.2. Studies that compare CM programs that include access to utilization data and the ability to follow patients across settings and episodes with CM that is limited to specific settings or time periods.	Intervention			Trials or observational studies. Program case studies.
	B.3. Studies to determine the modes of case manager contact (e.g., telehealth, telephone, in-person, home visits, in physician's office, etc.) that are most effective.	Intervention	Brown, 2012[6] Peikes, 2012[9]		Trials or observational studies. Program case studies.
	B.4. Studies that compare the impact of differences in training/education of case managers.	Intervention		Freund, 2011[23] NCMN, 2012[27]	Trials or observational studies. Program case studies.

Table 9. Topics for future research, recent and ongoing studies, and potential study designs (continued)

Domain	Specific Top-Tier Topics	Applicable PICOT Gap	Recent Studies	Ongoing Research	Potential Study Designs
C. Patient Selection/ Targeting	C.1. Studies that describe the characteristics of patients in CM programs that result in positive outcomes (benefits for patients or positive changes in utilization).	Intervention	Reilly, 2011[10]	Egede, 2011[24]	Subgroup analysis or risk profiling as part of trials or observational studies.
	C.2. Studies that examine the impact of tailoring CM activities based on patient characteristics.	Intervention		Crane, 2012[26] Freund, 2010[19] Versnel, 2011[25]	Head-to-head trials or observational studies that compare different approaches to CM.
	C.3. Studies that determine the effectiveness of aligning CM onset, intensity, composition and duration with the patient's needs.	Intervention			Head-to-head trials or observational studies that compare different approaches to CM.
D. Evaluation of CM Components	D.1. Studies that examine the role of evaluating the appropriateness of prescribed medications (using existing medication evaluation tools or involving a pharmacist) as part of CM (not simply evaluating adherence).	Intervention	Brown, 2012[6] Peikes, 2012[9]	Morales-Asencio, 2010[16]	Head-to-head trials or observational studies that compare CM with and without medications management.
	D.2. Studies that examine the role of including transitional care tools or models as part of CM.	Intervention	Brown, 2012[6] Peikes, 2012 [9]		Head-to-head trials or observational studies that compare CM with and without transitional care.
	D.3. Studies that examine the link between specific components of CM and specific outcomes (e.g., coordination of care and hospitalization; patient coaching and adherence).	Intervention	Baker, 2011[5] Peikes, 2012[9] Reilly, 2011[10] Ross, 2011[11] Wade, 2011[12]	Bachmann-Mettler, 2011[18] Freund, 2010[19] Kings Fund, 2012[20] Koopmans, 2012[21] Zwarenstein, 2011[17]	Head-to-head trials or observational studies that compare CM with different components such as factorial designs or studies with multiple treatment arms.
E. Research Design	E.1. Studies that describe longitudinal evaluation of the impact of CM, particularly for those with chronic illnesses and near the end of life.	Population			Trials with long-term followup. Observational studies - Registry Studies. - Retrospective studies of several years of records.
	E.2. Exposition of the pros and cons of various study designs that would be most productive at this stage (e.g., randomized, cluster-randomized, observational, community trials, qualitative).	Other			Methodological research. Expert consensus beyond what could be done within the scope of this project.

CM = case management; NCMN = National Case Management Network; PICOT = population, intervention, comparator, outcome, and timing
Empty cells denote no studies found.

Discussion

The CER concludes and stakeholders agreed that studies that (1) compare CM to usual care and (2) fail to specify, much less test, components of the intervention will not address the important questions about CM that have not been answered by existing research. This project identified five domains and 15 specific topics for future research that would contribute to answering remaining questions about CM.

The issues raised both in our assessment of prior research and our exploration of topics for future research are a reflection of the difficulties inherent in both implementing and evaluating complex, multifaceted, health services interventions. These interventions can be difficult to describe, and it can be challenging to disaggregate health services interventions into testable components. Efforts and initiatives that focus on implementation of care delivery models, ongoing quality improvement, and supporting systems of care (e.g., the learning health care organization and frameworks for implementation) may provide new perspectives that could inform future research and lead to innovative studies that help organizations provide care that will maximize the well being of people with serious illnesses and disabilities.

Our approach to identifying and prioritizing FRNs has limitations. While we attempted to engage stakeholders from a variety of perspectives, the small number of stakeholders involved makes it impossible to include the diversity of perspectives we know exist. Individuals were used to represent groups that likely include differences in priorities and opinions. In addition, limiting our literature scan to the period after that covered by the CER means that we did not identify studies that would have been excluded from the CER for reasons such as study design but which may address some of the specific topics prioritized by the stakeholders.

Conclusion

Based on the finding of the CER and stakeholder input, we identified 15 specific topics for future research that fit into five domains:

- *Global* issues related to definitions and standardization in research
- Details related to the *implementation of CM*
- Optimal *patient selection or targeting*
- Evaluating *components* of complex CM interventions
- *Research design* considerations

Recently published studies or ongoing projects were identified that corresponded to over half of the specific topics, but this body of research is unlikely to resolve the outstanding questions about CM. Rather this list suggests a future research agenda that differs significantly from research completed to date and suggests that future studies should focus on these more specific topics identified during the course of this project rather than repeating general assessments of CM.

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Acronyms and Abbreviations

AHRQ	Agency for Healthcare Research and Quality
CER	Comparative Effectiveness Review
CM	Case Management
EHC	Effective Health Care Program
EPC	Evidence-based Practice Center
FRN	Future Research Needs
IRB	Institutional Review Board
NCMN	National Case Management Network
NYU	New York University
PICOTS	Populations, interventions, comparators, outcomes, timing, and setting
U.S.	United States
WHO	World Health Organization

Appendix A. Stakeholder Invitation

[Stakeholder Name]
[Organization]
[Address]

[Date]
Dear [Stakeholder],
The Oregon Evidence-based Practice Center (EPC) was commissioned by the Agency for Healthcare Research and Quality (AHRQ) to prioritize future research needs in the area of *Outpatient Case Management for Adults with Medical Illness and Complex Care Needs*. We are interested in identifying case management topics that are important to stakeholders so that future research can address the most pressing needs and better inform clinical decision-making and health policy. **You have been nominated as a stakeholder with an interest in this area, and we would like to invite you to help us in this effort. Your participation would involve:**

1) **One 90-minute webinar. This will be offered on two dates.** The first webinar will be held on Thursday, May 31st from 11:00 am-12:30 pm Pacific Time (2:00 pm-3:30 pm Eastern Time). The second webinar will be held on Monday, June 11th from 10:00 am-11:30 am Pacific Time (1:00 pm-2:30 pm Eastern Time). You only need to be present during one of the sessions, and if you cannot make it to either, we may be able to arrange a telephone interview at another time. During the webinar, we will present the findings from the recently completed EPC evidence review, including information gaps that were identified and will facilitate a dialogue among participants to generate additional topics for inclusion in prioritizing future research. The goal of the webinar is to create a list of evidence gaps that will then be prioritized by yourself and other stakeholders.
2) **1-2 rounds of prioritizing identified topics using a web-based questionnaire.** Participants will then take part in a modified Delphi process to prioritize research topics. They will receive a link to a prioritizing questionnaire (and instructions) after the webinar. The questionnaire will take approximately 15-30 minutes to complete and will be ready approximately two weeks after the second webinar session. If a second round of ranking is required, it will take about 5-10 minutes of your time.

We hope you will be able to contribute your perspective and expertise in this effort to inform future research, decision-making, and policies regarding outpatient case management for adults with complex care needs.

Please confirm whether or not you will be able to participate in this project by [One week from when sent]. When confirming please indicate which webinar session you would like to attend or if you need to make other arrangements. Upon agreement to participate, you will be requested to complete an EPC conflict of interest disclosure form. We will send background materials to stakeholders prior to the webinar sessions

If you have any questions, or would like additional information, please contact Annette Totten at totten@ohsu.edu or Jesse Wagner at wagnerje@ohsu.edu or (503) 494-4592.

Sincerely,

Appendix B. Online Questionnaire

Case Management Future Research Needs

Future Research Needs: Case Management

This questionnaire is a key step in the Future Research Needs project about Case Management for Adults with Serious Illnesses. Your participation is voluntary, and we appreciate your willingness to help.

In the following pages you are asked 1) to rate the topics that were raised in the systematic review, the webinars, interviews and discussions, and 2) to answer selected open-ended questions.

You may skip any question(s) you prefer not to answer. The black bar at the top of each page indicates your progress through the questionnaire.

If you have any questions or problems with this questionnaire, please contact:
Jesse Wagner, 503-494-4592, wagnerje@ohsu.edu

Case Management Future Research Needs

Section I: Background

***These questions are required for tracking, follow-up and summary reporting. No answer will be attributed to any specific person.**

1. Please fill out the information below.

Name:

Organization:

***2. We recognize that many people have multiple roles and different perspectives based on different roles. What is the primary perspective that you will use in responding to these questions?**

- Consumer/Patient Advocate
- Clinician
- Policymaker
- Researcher
- Funder of Research
- Other

Other (please specify)

Case Management Future Research Needs

Section II: Topics for Prioritization

The following items reflect research gaps identified in the comparative effectiveness review on Outpatient Case Management for Adults with Medical Illness and Complex Care Needs, via the two webinars we held and through additional interviews and input.

Please rate each topic from "Lowest Priority" to "Highest Priority" in terms of how important research on this topic would be to advancing the field of case management.

As you go through the items please consider the following criteria:

- Importance
- Desirability of new research
- Feasibility
- Potential impact

Case Management Future Research Needs

Section IIA: Patients

For each of the topics listed regarding PATIENTS, please rate the potential topics on a six-point scale from lowest to highest priority. Think about how future research can best advance the field of case management and contribute to the well-being of patients.

	Lowest Priority					Highest Priority
1. Studies that describe the characteristics of patients in case management (CM) programs that result in positive outcomes (benefits for patients or positive changes in utilization).	○	○	○	○	○	○
2. Studies that assess the use of risk assessment tools for choosing patients most likely to benefit from CM.	○	○	○	○	○	○
3. Studies of CM for patients with multiple comorbidities and issues (i.e., studies that do not exclude patients based on severity, diagnosis, or other aspects of need).	○	○	○	○	○	○
4. Studies of whether the known risk factors for rehospitalization (e.g., functional status, social support, number of past hospitalizations) would be useful in targeting CM.	○	○	○	○	○	○
5. Studies with large sample sizes (more power) – e.g., large observational cohort studies, large trials and/or registries.	○	○	○	○	○	○
6. Studies to determine the impact of patient literacy (or the case manager's ability to address patient literacy) on effectiveness of CM.	○	○	○	○	○	○
7. Studies to assess the impact of patient motivation (e.g., reason for enrollment, personal efficacy).	○	○	○	○	○	○
8. Studies to assess the impact of patient activation (a specific measure that includes confidence, engagement, skills and knowledge) on the effectiveness of CM.	○	○	○	○	○	○
9. Studies that compare characteristics of patients who choose to participate with those who choose not to participate in CM.	○	○	○	○	○	○
10. Studies that compare CM programs that automatically enroll patients with programs where patients have to choose to enroll (i.e., opt-in vs. opt-out programs).	○	○	○	○	○	○
11. Studies that describe longitudinal evaluation of the impact of CM, particularly for those with chronic illnesses and near the end of life.	○	○	○	○	○	○
12. Studies that determine what strategies are most effective to engage persons in CM who are otherwise disengaged from the health care system.	○	○	○	○	○	○

Please add any explanations or comments below:

Case Management Future Research Needs

Section IIB: Case Managers

For each of the topics listed regarding CASE MANAGERS, please rate each topic from "Lowest Priority" to "Highest Priority" in terms of how important research on this topic would be to advancing the field of case management.

	Lowest Priority					Highest Priority
1. Studies of the impact/importance of the characteristics of the individual serving in the role of case manager (individual traits such as personality, motivation, etc.).	○	○	○	○	○	○
2. Studies to evaluate what is the right caseload for case managers.	○	○	○	○	○	○
3. Studies that compare the impact of differences in training/education of case managers.	○	○	○	○	○	○
4. Studies that compare the impact of case managers from different disciplines (e.g., nurses, social workers, pharmacists).	○	○	○	○	○	○
5. Studies that compare case managers integrated into teams versus case managers working alone.	○	○	○	○	○	○
6. Studies that examine the relationship of the case manager with the patients and families and how that relationship impacts outcomes.	○	○	○	○	○	○
7. Studies that examine the role of primary care providers in identifying patients who could benefit from CM.	○	○	○	○	○	○
8. Studies that assess how to keep case managers focused on the highest-impact components of CM (e.g., supervision and/or incentives).	○	○	○	○	○	○

Please feel free to add any explanations or comments related to your answers below:

Case Management Future Research Needs

Section IIC: Case Management Intervention

For each statement below regarding the CASE MANAGEMENT INTERVENTION, please rate each topic from "Lowest Priority" to "Highest Priority" in terms of how important research on this topic would be to advancing the field of case management.

At the end of this section please feel free to provide further comments regarding your answers in the space provided.

	Lowest Priority					Highest Priority
1. Studies that examine the impact of tailoring CM activities based on patient characteristics.	○	○	○	○	○	○
2. Studies that compare the effectiveness of standardized CM protocols with more flexible CM protocols.	○	○	○	○	○	○
3. Studies to assess whether CM protocols are followed (e.g., fidelity assessments to document whether CM is actually implemented as planned).	○	○	○	○	○	○
4. Studies that compare the effectiveness of CM focused on patient education with CM focused on direct patient support activities (e.g., coaching, coordinating care).	○	○	○	○	○	○
5. Studies that compare different ways to provide patient education within CM.	○	○	○	○	○	○
6. Studies of the impact of patient-provider interaction techniques or models (e.g., motivational interviewing, coaching, or stages of change) on the effectiveness of CM.	○	○	○	○	○	○
7. Studies that examine the link between specific components of case management and specific outcomes (e.g., coordination of care and hospitalization; patient coaching and adherence).	○	○	○	○	○	○
8. Studies that examine the role of comprehensive medical management in CM (e.g., ability of case manager to make clinical recommendations or decisions, such as adjusting medications or treatments).	○	○	○	○	○	○
9. Studies that examine the role of evaluating the appropriateness of prescribed medications (using existing medication evaluation tools or involving a pharmacist) as part of CM (not simply evaluating adherence).	○	○	○	○	○	○
10. Studies that examine the role of including transitional care tools or models as part of CM.	○	○	○	○	○	○
11. Studies that compare CM programs that include access to utilization data and the ability to follow patients across settings and episodes with CM that is limited to specific settings or time periods.	○	○	○	○	○	○
12. Studies that compare CM programs that vary in intensity.	○	○	○	○	○	○
13. Studies to assess potential ways to standardize CM.	○	○	○	○	○	○
14. Studies that establish criteria for rating the quality of CM programs (so that quality of CM programs and the effectiveness of programs at different levels of quality can be compared).	○	○	○	○	○	○
15. Studies that establish the core components/minimum elements needed for CM.	○	○	○	○	○	○
16. Studies to assess the impact of the use of information technology on the effectiveness of CM.	○	○	○	○	○	○
17. Studies of alternative CM models or new models of care that include CM.	○	○	○	○	○	○
18. Studies that compare CM programs with different specific missions or focuses (e.g., focus on preventing major events like hospitalization versus supporting behavior change).	○	○	○	○	○	○
19. Studies to determine the modes of case manager contact (e.g., telehealth, telephone, in-person, home visits, in physician's office, etc.) that are most effective.	○	○	○	○	○	○
20. Studies that determine the effectiveness of different forms of all of the components of CM (including assessment, evidence-based care planning, patient/family education, engagement/coaching for self-management, coordination of care, proactive monitoring, integrating with community agencies).	○	○	○	○	○	○

Case Management Future Research Needs

21. Studies that determine the effectiveness of aligning CM onset, intensity, composition and duration with the patient's needs.

Please feel free to add any explanations or comments related to your answers below:

Case Management Future Research Needs

Section IID: Comparator and Outcomes

For each statement below regarding the COMPARATOR and OUTCOMES, please rate each topic from "Lowest Priority" to "Highest Priority" in terms of how important research on this topic would be to advancing the field of case management.

	Lowest Priority					Highest Priority
1. Studies that compare CM with other non-CM interventions designed to achieve similar outcomes.	○	○	○	○	○	○
2. Studies that compare the effectiveness of different CM components rather than compare CM with usual care.	○	○	○	○	○	○
3. Studies of how CM can be made more efficient so that it is either cost neutral or generates savings.	○	○	○	○	○	○
4. Studies in which resource utilization is the primary outcome for CM.	○	○	○	○	○	○
5. Studies of the impact of CM on families of patients and whether that impact is related to other outcomes.	○	○	○	○	○	○
6. Studies that examine the influence of family caregivers on CM outcomes.	○	○	○	○	○	○
7. Studies of other outcomes of CM, such as whether or not it reduces pressure on other parts of the system (i.e., does it make physician's work easier?).	○	○	○	○	○	○
8. Studies with pragmatic standards for measuring and reporting relevant outcomes, such as utilization, all stakeholders' costs, quality of care, quality of life, and satisfaction.	○	○	○	○	○	○

Please feel free to add any explanations or comments related to your answers below:

Case Management Future Research Needs

Section IIE: Timing and Setting

For each statement below regarding TIMING and SETTING, please rate each topic from "Lowest Priority" to "Highest Priority" in terms of how important research on this topic would be to advancing the field of case management.

	Lowest Priority					Highest Priority
1. Studies that examine whether timing of CM after hospital discharge is associated with effectiveness of CM.	○	○	○	○	○	○
2. Studies that evaluate how long patients should be enrolled in CM and what should trigger disenrollment.	○	○	○	○	○	○
3. Studies that examine different settings and organizations for case management (e.g., role of a single person versus part of primary care).	○	○	○	○	○	○
4. Studies of how CM can be incorporated into Accountable Care Organizations.	○	○	○	○	○	○
5. Studies that compare the effectiveness of CM based in different types of organizations (e.g., insurer, non-profit, hospital-based, primary care provider based, specialist provider based).	○	○	○	○	○	○
6. Studies that examine the effects of different payment approaches (e.g., capitation vs. shared savings vs. fee for service).	○	○	○	○	○	○
7. Studies to assess effects of CM in high health services utilization versus low-utilization geographic regions.	○	○	○	○	○	○
8. Studies that compare CM in integrated systems with CM in organizations that are not part of an integrated system.	○	○	○	○	○	○
9. Studies of CM in managed care/health plans/non-academic settings.	○	○	○	○	○	○

Please feel free to add any explanations or comments related to your answers below:

Case Management Future Research Needs

Section IIF: Other

Please rate each topic from "Lowest Priority" to "Highest Priority" in terms of how important research on this topic would be to advancing the field of case management.

	Lowest Priority					Highest Priority
1. Studies that establish pragmatic standards for measuring and reporting CM characteristics and outcomes that should be routinely reported in journal articles/study protocols about CM.	○	○	○	○	○	○
2. Studies that establish clear definitions of specific models of CM based, for example, on their components, intensity and duration.	○	○	○	○	○	○
3. Exposition of the pros and cons of various study designs that would be most productive at this stage (e.g., randomized, cluster-randomized, observational, community trials, qualitative).	○	○	○	○	○	○

Please feel free to add any explanations or comments related to your answers below:

Case Management Future Research Needs

Section III: Additional Input

During the webinars, several fundamental questions were raised in addition to the specific topics for future research. We would like to include these in our report. In order to give everyone an opportunity to contribute to these we are asking three open-ended questions. We will use the answers to supplement information from the webinar discussions.

How should future research on CM be different from current research in order for it to contribute to optimal care over time for adults with serious medical illnesses? [This could be about methods, scope or topics]

One problem mentioned frequently in the webinars (and in the Comparative Effectiveness Review) is that studies often do not measure or report important aspects of CM interventions. With that in mind, please list five to ten KEY ITEMS that should be MEASURED AND/OR REPORTED in all future CM studies.

Another problem with current CM studies that frequently arose during our conversations is that there is not a common definition of case management applied across studies. What are the KEY ELEMENTS that should be included in a standardized definition of CM?

We have conducted a literature scan in order to identify ongoing and recently published studies but want to make sure that we have not missed anything. Please list below any studies of CM you are aware of that are ongoing or due to start soon.

Case Management Future Research Needs

Feel free to provide any additional comments below (optional):

Case Management Future Research Needs

Thank You and Follow-up

Thank you once again for your participation in this important project that will help direct future case management research! As previously stated, we may conduct one further – much shorter – round of prioritization to narrow down the final 10-15 topics. In addition, we will let you know when the report posts to AHRQ's website for public comments, and we will provide you with the link for the final report. Your participation has been tremendously helpful and we are very grateful for your time. Please direct any further questions or comments to Annette Totten at totten@ohsu.edu or Jesse Wagner at wagnerje@ohsu.edu.

Appendix C. Detailed Search Strategy for Recent and Ongoing Studies

OvidSP MEDLINE(R) and OvidSP OLDMEDLINE(R) 1946 to June Week 1 2012,

OvidSP MEDLINE(R) In-Process & Other Non-Indexed Citations June 13, 2012
Date searched: 06/13/2012

1	exp Patient Care Planning/	48333
2	((manag$ or oversee$ or supervis$ or coordin$) adj5 ((patient$ adj3 care) or (case or cases))).mp.	37989
3	1 and 2	8845
4	limit 3 to english language	8335
5	limit 4 to "all adult (19 plus years)"	2590
6	limit 4 to "all child (0 to 18 years)"	1284
7	5 or 6	3323
8	4 not 7	5012
9	8 or 5	7602
10	9 and (201108* or 201109* or 201110* or 201111* or 201112* or 2012*).ed.	287

CINAHL Plus with Full Text (1937-Wednesday, June 13, 2012)
Date searched: 06/13/2012

S5	S3 and S4	**Search modes** - Boolean/Phrase	400
S4	((manag* or oversee* or supervis* or coordin*) N5 ((patient* N3 care) or (case or cases)))	**Search modes** - Boolean/Phrase	21561
S3	S1 or S2	**Limiters** - English Language; Exclude MEDLINE records; Published Date from: 20110801-20121231 **Search modes** - Boolean/Phrase	400
S2	MH "Case Managers"	**Search modes** - Boolean/Phrase	2102
S1	MH "Case Management"	**Search modes** - Boolean/Phrase	11159

OvidSP EBM Reviews - Cochrane Central Register of Controlled Trials June 2012
Date searched: 06/13/2012

1	case manag$.ti,hw,kw.	646
2	limit 1 to yr="2011 -Current"	30

OvidSP EBM Reviews - Cochrane Database of Systematic Reviews 2005 to May 2012
Date searched: 06/13/2012

1	case manag$.ti,kw.	9
2	case manag$.oh,tw.	134
3	1 or 2	134
4	limit 3 to last year	31

OvidSP EBM Reviews - Database of Abstracts of Reviews of Effects 2nd Quarter 2012
Date searched: 06/13/2012

1	case manag$.ti,kw,tw.	104
2	limit 1 to last year	104

ClinicalTrials.gov
Date searched: 06/13/2012

"case management" OR "case manager" OR "nurse case manager" OR "care managers" OR "nurse case manager" | Adult, Senior | received from 08/15/2011 to 06/14/2012 | updated from 08/15/2011 to 06/14/2012

Current Controlled Trials
Date searched: 06/14/2012

Case management OR case manager

International Clinical Trials Registry Platform Search Portal (ICTRP)
Date searched: 06/14/2012

Title: case management OR case manager
Also searched: Intervention: case management OR case manager
Date of registration: 18/08/2011 and 14/06/2012

Scopus (1960-present)
Date searched: 06/14/2012

TITLE ABS KEY(case **PRE/1** manage***) AND DOCTYPE(**cp**) AND SUBJAREA(**mult **OR** medi **OR** nurs **OR** vete **OR** dent **OR** heal **OR** mult **OR** arts **OR** busi **OR** deci **OR** econ **OR** psyc **OR** soci**) AND PUBYEAR >** 2010

NIH Research Portfolio Online Reporting Tools (NIHRePORTER)
Date searched: 06/14/2012

Text Search (Logic): "case management" OR "case manager"
Award Notice Date > 08/15/2011

Health Services Research Project in Progress (HSRProj)
Date searched: 06/14/2012

("case management" OR "case manager")
Project status = Ongoing : Initial Year Range = 2011 - 2012

Agency for Healthcare Research and Quality Grants On-Line Database (AHRQ Gold)
Date searched: 06/14/2012

All 3 searches: AHRQ Research Grants database | HHS Recovery Act Projects | AHRQ Working Papers:
abstract text|project description text|abstract/research text: "case management" OR "case manager"

Foundation Center Directory Online
Date searched: 06/14/2012

Keyword search: "case management" OR "case manager"
Year Authorized: From 2011 to 2012
Subjects: health care, health organizations, heart & circulatory diseases, heart & circulatory research, medical care, outpatient services; medical care, rehabilitation; medical care, community health systems; medical research; cancer; diabetes; nursing care; public health; research; senior continuing care; substance abuse prevention; substance abuse, services; terminal illness, people with;
Also searched Types of Support: research

Appendix D. Detailed Topic Rankings Ordered by Mean Score[a]

Rank	Topic	Mean Score	High Priority: Ranked 5-6 % (n)	Medium Priority: Ranked 3-4 % (n)	Low Priority: Ranked 1-2 % (n)
1	Studies that establish clear definitions of specific models of CM based, for example, on their components, intensity and duration.	5.67	100% (9)	0% (0)	0% (0)
2	Studies that establish pragmatic standards for measuring and reporting CM characteristics and outcomes that should be routinely reported in journal articles/study protocols about CM.	5.22	78% (7)	22% (2)	0% (0)
3	Studies of how CM can be made more efficient so that it is either cost neutral or generates savings.	5.11	78% (7)	11% (1)	11% (1)
4	Studies with pragmatic standards for measuring and reporting relevant outcomes, such as utilization, all stakeholders' costs, quality of care, quality of life, and satisfaction.	5.11	67% (6)	33% (3)	0% (0)
5	Studies that compare CM programs that include access to utilization data and the ability to follow patients across settings and episodes with CM that is limited to specific settings or time periods.	5	78% (7)	11% (1)	11% (1)
6	Studies that describe the characteristics of patients in case management (CM) programs that result in positive outcomes (benefits for patients or positive changes in utilization).	4.89	78% (7)	11% (1)	11% (1)
7	Studies that describe longitudinal evaluation of the impact of CM, particularly for those with chronic illnesses and near the end of life.	4.89	78% (7)	11% (1)	11% (1)
8	Studies that examine the role of evaluating the appropriateness of prescribed medications (using existing medication evaluation tools or involving a pharmacist) as part of CM (not simply evaluating adherence).	4.78	67% (6)	33% (3)	0% (0)
9	Studies that examine the role of including transitional care tools or models as part of CM.	4.78	56% (5)	44% (4)	0% (0)
10	Studies to determine the modes of case manager contact (e.g., telehealth, telephone, in-person, home visits, in physician's office, etc.) that are most effective.	4.78	67% (6)	22% (2)	11% (1)
11	Exposition of the pros and cons of various study designs that would be most productive at this stage (e.g., randomized, cluster-randomized, observational, community trials, qualitative).	4.78	67% (6)	33% (3)	0% (0)
12	Studies that examine the impact of tailoring CM activities based on patient characteristics.[b]	4.75	75% (6)	0% (0)	25% (2)

Rank	Topic	Mean Score	High Priority: Ranked 5-6 % (n)	Medium Priority: Ranked 3-4 % (n)	Low Priority: Ranked 1-2 % (n)
13	Studies that determine the effectiveness of aligning CM onset, intensity, composition and duration with the patient's needs.	4.67	67% (6)	22% (2)	11% (1)
14	Studies that compare the impact of differences in training/education of case managers.	4.56	56% (5)	33% (3)	11% (1)
15	Studies that examine the link between specific components of case management and specific outcomes (e.g., coordination of care and hospitalization; patient coaching and adherence).	4.56	56% (5)	33% (3)	11% (1)
16	Studies that assess the use of risk assessment tools for choosing patients most likely to benefit from CM.	4.44	44% (4)	56% (5)	0% (0)
17	Studies of CM for patients with multiple comorbidities and issues (i.e., studies that do not exclude patients based on severity, diagnosis, or other aspects of need).	4.44	67% (6)	22% (2)	11% (1)
18	Studies that compare the effectiveness of standardized CM protocols with more flexible CM protocols.	4.44	56% (5)	44% (4)	0% (0)
19	Studies of how CM can be incorporated into Accountable Care Organizations.	4.44	56% (5)	33% (3)	11% (1)
20	Studies that examine the effects of different payment approaches (e.g., capitation vs. shared savings vs. fee for service).	4.44	56% (5)	22% (2)	22% (2)
21	Studies with large sample sizes (more power) – e.g., large observational cohort studies, large trials and/or registries.	4.33	44% (4)	44% (4)	11% (1)
22	Studies of alternative CM models or new models of care that include CM.	4.33	56% (5)	33% (3)	11% (1)
23	Studies that evaluate how long patients should be enrolled in CM and what should trigger disenrollment.	4.33	56% (5)	33% (3)	11% (1)
24	Studies that examine the role of comprehensive medical management in CM (e.g., ability of case manager to make clinical recommendations or decisions, such as adjusting medications or treatments).	4.22	56% (5)	22% (2)	22% (2)
25	Studies that examine whether timing of CM after hospital discharge is associated with effectiveness of CM.	4.22	44% (4)	33% (3)	22% (2)
26	Studies that examine different settings and organizations for case management (e.g., role of a single person versus part of primary care).	4.22	56% (5)	33% (3)	11% (1)

Rank	Topic	Mean Score	High Priority: Ranked 5-6 % (n)	Medium Priority: Ranked 3-4 % (n)	Low Priority: Ranked 1-2 % (n)
27	Studies of whether the known risk factors for rehospitalization (e.g., functional status, social support, number of past hospitalizations) would be useful in targeting CM.[b]	4.13	50% (4)	25% (2)	25% (2)
28	Studies that compare case managers integrated into teams versus case managers working alone.	4.11	67% (6)	11% (1)	22% (2)
29	Studies that examine the relationship of the case manager with the patients and families and how that relationship impacts outcomes.	4.11	44% (4)	44% (4)	11% (1)
30	Studies to assess whether CM protocols are followed (e.g., fidelity assessments to document whether CM is actually implemented as planned).	4.11	56% (5)	33% (3)	11% (1)
31	Studies of the impact of patient-provider interaction techniques or models (e.g., motivational interviewing, coaching, or stages of change) on the effectiveness of CM.	4.11	44% (4)	33% (3)	22% (2)
32	Studies that compare CM programs that vary in intensity.	4.11	56% (5)	22% (2)	22% (2)
33	Studies that establish the core components/minimum elements needed for CM.	4.11	56% (5)	11% (1)	33% (3)
34	Studies that determine the effectiveness of different forms of all of the components of CM (including assessment, evidence-based care planning, patient/family education, engagement/coaching for self-management, coordination of care, proactive monitoring, integrating with community agencies).	4.11	56% (5)	22% (2)	22% (2)
35	Studies that compare the effectiveness of different CM components rather than compare CM with usual care.	4.11	56% (5)	22% (2)	22% (2)
36	Studies to assess effects of CM in high health services utilization versus low-utilization geographic regions.	4	33% (3)	56% (5)	11% (1)
37	Studies to assess the impact of patient activation (a specific measure that includes confidence, engagement, skills and knowledge) on the effectiveness of CM.	3.89	44% (4)	33% (3)	22% (2)
38	Studies that determine what strategies are most effective to engage persons in CM who are otherwise disengaged from the health care system.	3.89	44% (4)	33% (3)	22% (2)
39	Studies that compare the impact of case managers from different disciplines (e.g., nurses, social workers, pharmacists).	3.89	33% (3)	44% (4)	22% (2)

Rank	Topic	Mean Score	High Priority: Ranked 5-6 % (n)	Medium Priority: Ranked 3-4 % (n)	Low Priority: Ranked 1-2 % (n)
40	Studies that compare the effectiveness of CM focused on patient education with CM focused on direct patient support activities (e.g., coaching, coordinating care).	3.89	44% (4)	22% (2)	33% (3)
41	Studies of the impact of CM on families of patients and whether that impact is related to other outcomes.	3.89	44% (4)	22% (2)	33% (3)
42	Studies that examine the influence of family caregivers on CM outcomes.	3.89	22% (2)	67% (6)	11% (1)
43	Studies of other outcomes of CM, such as whether or not it reduces pressure on other parts of the system (i.e., does it make physician's work easier?).	3.89	22% (2)	78% (7)	0% (0)
44	Studies that compare the effectiveness of CM based in different types of organizations (e.g., insurer, non-profit, hospital-based, primary care provider based, specialist provider based).	3.89	44% (4)	44% (4)	11% (1)
45	Studies that compare CM in integrated systems with CM in organizations that are not part of an integrated system.	3.89	44% (4)	33% (3)	22% (2)
46	Studies that examine the role of primary care providers in identifying patients who could benefit from CM.	3.67	22% (2)	56% (5)	22% (2)
47	Studies that assess how to keep case managers focused on the highest-impact components of CM (e.g., supervision and/or incentives).	3.67	22% (2)	44% (4)	33% (3)
48	Studies that establish criteria for rating the quality of CM programs (so that quality of CM programs and the effectiveness of programs at different levels of quality can be compared).	3.67	44% (4)	11% (1)	44% (4)
49	Studies in which resource utilization is the primary outcome for CM.	3.67	22% (2)	56% (5)	22% (2)
50	Studies to evaluate what is the right caseload for case managers.	3.56	44% (4)	22% (2)	33% (3)
51	Studies to assess the impact of the use of information technology on the effectiveness of CM.	3.56	22% (2)	67% (6)	11% (1)
52	Studies to determine the impact of patient literacy (or the case manager's ability to address patient literacy) on effectiveness of CM.	3.44	22% (2)	56% (5)	22% (2)
53	Studies to assess the impact of patient motivation (e.g., reason for enrollment, personal efficacy).	3.44	22% (2)	56% (5)	22% (2)

Rank	Topic	Mean Score	High Priority: Ranked 5-6 % (n)	Medium Priority: Ranked 3-4 % (n)	Low Priority: Ranked 1-2 % (n)
54	Studies of the impact/importance of the characteristics of the individual serving in the role of case manager (individual traits such as personality, motivation, etc.).	3.44	44% (4)	11% (1)	44% (4)
55	Studies that compare CM with other non-CM interventions designed to achieve similar outcomes.	3.44	33% (3)	33% (3)	33% (3)
56	Studies that compare CM programs that automatically enroll patients with programs where patients have to choose to enroll (i.e., opt-in vs. opt-out programs).	3.33	22% (2)	44% (4)	33% (3)
57	Studies to assess potential ways to standardize CM.	3.22	33% (3)	22% (2)	44% (4)
58	Studies that compare CM programs with different specific missions or focuses (e.g., focus on preventing major events like hospitalization versus supporting behavior change).	3.22	22% (2)	33% (3)	44% (4)
59	Studies of CM in managed care/health plans/non-academic settings.	3.22	22% (2)	33% (3)	44% (4)
60	Studies that compare different ways to provide patient education within CM.	3	11% (1)	56% (5)	33% (3)
61	Studies that compare characteristics of patients who choose to participate with those who choose not to participate in CM.	2.67	0% (0)	44% (4)	56% (5)

[a] Mean score is out of a possible 6. Some percentages do not equal 100 due to rounding.
[b] n=8 for these two topics due to a stakeholder skipping them on the questionnaire.
Note: CM=case management

Appendix E. Responses to Open-Ended Question: What Aspects of Case Management Should Be Measured and Reported?

	Stakeholder Responses	Topic Code
1	Whether [the intervention] was implemented as designed	Implementation
2	Intensity/duration	Implementation
3	Duration	Implementation
4	Termination criteria	Implementation
5	Type and frequency of interactions between patient/family and CM and where relevant other members of the team.	Implementation
6	The frequency with which the contacts are made	Implementation
7	Mode of contact (phone vs. in-person)	Implementation
8	How the contact is made and what is done at each contact. e.g. two in-person visits for assessment and motivational interviewing with 5 intervening phone calls for coaching and patient education.	Implementation
9	Access to data	Implementation
10	Might actually do very specific observational studies examining the specifics of how case managers function, integrate, manage data, etc.	implementation
11	What the intervention was	CM description/components
12	Approach to education	CM description/component
13	How medication management is done	CM description/component
14	Care plan details (what is covered, what is shared w/ patients, usual care providers, and care manager)	CM description/component
15	Greater specificity of all aspects of the interventions	CM description/component
16	Detail of the interventions provided	CM description/component
17	Medication management (not just adherence)	CM description/components
18	Family caregiver interventions	CM description/components
19	In-patient intervention	CM description/components
20	Program components	CM description/components
21	What happens after [24 hrs]--care versus care coordination	CM description/components
22	Interaction with usual care providers	Environment/context
23	Site/context	Environment/context
24	Implementation process/challenges	Environment/context
25	Type and frequency of interactions between and among team members with primary care provider	Environment/context
26	How CM fits into the overall design of the clinic	Environment/context
27	Clinic design into which CM fits best	Environment/context
28	Leadership and culture issues critical to CM success	Environment/context
29	The cost outcome	Cost
30	All program costs	Cost
31	ROI	Cost
32	Long term projection of cost changes (regression to mean?)	Cost
33	Original characteristics of the patient	Patient selection/characteristics
34	Patient selection criteria	Patient selection/characteristics
35	Selection criteria for CM	Patient selection/characteristics
36	Identification of population targeted for CM	Patient selection/characteristics
37	Goals	Outcomes: general
38	Effects on all stakeholders	Outcomes: general

	Stakeholder Responses	Topic Code
39	Major system impact of CM (i.e., hospitalizations, medication compliance)	Outcomes: general
40	The clinical outcome	Clinical outcomes
41	Quality measures including patient/family satisfaction, impact of interventions on patient/family[a]	Clinical outcomes
42	Background/training of CMs	Case manager characteristics
43	Effective care manager requirements	Case manager characteristics
44	Identification of all members of the team and roles/responsibilities	Case manager characteristics
45	Caseload	Caseload
46	Case loads	Caseload
47	Quality measures including patient/family satisfaction, impact of interventions on patient/family[a]	Patient satisfaction
48	Patient satisfaction as an outcome	Patient satisfaction
49	The manner in which multicultural issues are addressed	Multicultural
50	CM as a continuous improvement method	Other
51	What happens in 24 hours	Not coded
52	Proportion incoming vs. outgoing contacts	Not coded

[a] Multiple codes applied to this response

Appendix F. Recently Completed Studies/Projects on the Effectiveness of Case Management

First Author, Year	Objective	Study Design	Population	Intervention	Results	Corresponding Research Needs Domain and Topics
Baker, 2011[1]	To evaluate the impact of CM integrated with a telehealth tool on costs	Controls: usual care matched to CM patients, pre-post design	High cost Medicare beneficiaries	CM and a telehealth tool	Savings of approximately 7.7 to 13.3%	B.1: Increase efficiency D.3 Evaluation of CM components
Brown, 2012[2]	To identify program elements in CM that reduce hospitalizations	Subgroup analysis of Medicare Demonstration project	Patients at high risk of hospitalization	CM associated with reduction of hospitalizations	Identified six elements of CM programs that reduced hospitalizations.	B.3 Implementations: Modes of communication D.1 Medications management D.2 Transition care
Hines, 2011[3]	To examine and redefine the roles of HIV case managers to improve care	Case studies and surveys	People with HIV served by state programs	CM for people with HIV	CM activities and functions were delineated and participants developed a revised model of coordination among state and local programs.	B.1 Increase efficiency B.4 Case manager training
Hughes, 2011[4]	To identify similarities and differences in the services in goals, function and tasks of two programs.	Policy analysis and surveys	Organizations (local authorities and primary care trusts in the UK)	Care management and case management as implemented in UK	Both were designed to shift care from high cost services to home. They differ in terms of more specific goals, the people they serve, and the staff used.	A.1 Definitions of models
Peikes, 2012[5]	To determine the effectiveness of a redesigned CM program	RCT with a redesigned CM intervention	Medicare beneficiaries in demonstration project	Redesign included local care managers, stronger transitional care and medication management, more in-person contact, and more thorough assessments.	Hospitalizations were decreased without increasing spending. Spending was reduced 9.7% in the higher risk group. Use of CM assistants for lower risk patients contributed to financial sustainability.	B.1 Increase efficiency B.3 Modes of communication B 4 Case manager training D.1 Medication management D.2 Transition care D.3 Link components and outcomes

First Author, Year	Objective	Study Design	Population	Intervention	Results	Corresponding Research Needs Domain and Topics
Reilly, 2011[6]	To evaluate the implementation and impact of case management	Survey of practice manager sand retrospective cohort analysis of patient records	Primary care patients with long-term conditions	CM as delivered in 10 primary care practices	Detailed description of CM in the 10 sites, including similarities and differences across sites. Features of CM had only a modest effect on effectiveness.	A.1 Definitions of CM models C.1 Patient targeting D.3 Link components and outcomes
Ross, 2011[7]	To examine how case management can be implemented successfully	Literature review and case studies	Programs that have successfully implemented case management	Long term case management programs, mostly in primary care	Identified core components of case management and factors associated with successful case management.	A.1 Definitions of CM models B.2 Integration B.4 Case manager training D. 3 Link components and outcomes
Wade, 2011[8]	Assess nurse case management with telemonitoring	RCT	Elderly patients with heart failure	Telemonitoring added to CM	No difference in clinical outcomes or quality of life—no incremental benefit.	D.3 Link components and outcomes
Mayo, 2011[9]	To determine impact of CM on any patient outcomes, allowing diversity of outcomes across patients.	Reanalysis of RCT	Stroke patients	Nurse case management	Patients in CM were more likely (OR 1.41) to have one or more positive outcome. Comparisons on each outcome found no significant difference.	None
Rinke, 2012[10]	To pilot test CM for frequent users of Emergency Medical Services	Pre-post (n=10)	Frequent EMS users	Case manager with nurse liaison backup	Transport responses and costs decreased compared to predictions based on prior use.	None

Note: CM=case management; EMS=emergency medical services; HIV=human immunodeficiency virus; RCT=randomized controlled trial.

Appendix G. Ongoing Studies/Projects on the Effectiveness of Case Management

Investigator, Year	Objective	Study Design	Population	Completion Information	Corresponding Research Needs Domain & Topics
Bachmann-Mettler , 2011[11]	To determine the impact of CM in cancer rehab in terms of impact on patient quality of life with an emphasis on self-management	Randomized trial	Patients with cancer	End of data collection: 12/31/2011	D.3 Link components and outcomes
Crane[12]	To use patient reported outcomes and customized case management to improve adherence and health status for patients with HIV	Randomized trial	Patients with HIV	End of data collection: 6/2013; Study completion 1/2014	C.2 Tailoring CM based on patient characteristics
Egede, 2011 [13]	To test the effectiveness of technology assisted CM for low income rural adults with type 2 diabetes	Randomized trial	Patients with type 2 diabetes	End of data collection: June 2015	C.1 Patient targeting (exploratory analysis)
Freund, 2010[14]	To assess clinical effects and economic implications of CM	Systematic review of randomized and non randomized trials of CM compared with routine care	Adults with at least one chronic condition in primary care	Due for completion 8/2012 per Centre for Reviews and Dissemination. No completed review located.	C.1 Patient targeting (planned subgroup analysis by chronic disease) D.3 Link components and outcomes
Freund, 2011[15]	To determine the impact of CM conducted by Health Care Assistants in Primary care on all-cause hospitalization and quality of life	Cluster randomized trial (primary care practices will be randomized)	Primary care patients with diabetes, COPD, CHF or combination	End of data collection: 12/31/2012	B.4 Case manager training
King's Fund, 2012[16]	To identify how to best apply care co-ordination in practice	Interviews, focus groups, observations, text analyses	Primary Care patients in five sites selected as examples of effective care coordination	Due for completion late 2013	B.1: Increase efficiency D.3 Link components and outcomes

Investigator, Year	Objective	Study Design	Population	Completion Information	Corresponding Research Needs Domain & Topics
Koopmans, 2011[17]	To evaluate the effect of the CareWell program	Prospective cohort	Community-dwelling frail older people	End of data collection: 1/2013	B.1: Increase efficiency D.3 Link components and outcomes
Morales-Asencio, 2010[18]	To develop CM interventions based on patient experience and needs	1. Interviews with patients and families 2. Delphi with 50 clinicians/experts	Patients with COPD or heart failure	No additional information located	A.1 Definitions of CM models D.3 Link components and outcomes
National Case Management Network, 2012[19]	To develop core competencies for case management providers	Interviews, expert consensus, discussion at annual conference	Case management across all sectors in Canada	To be completed Winter 2013	A.1 Definitions of CM models B.4 Case manager training
Raven, 2012[20]	To improve care and reduce health care expenditures by an intensive CM intervention.	Cluster randomized trial	High-risk, high cost fee for service Medicaid services users	End of data collection: 9/2011; Study completion 12/2012	B.1: Increase efficiency
Versnal, 2011[21]	To examine the effectiveness of CM in addition to a diabetes management program on quality of care	Randomization of patients already in diabetes program to either additional CM or usual care	Type 2 Diabetes and other comorbidities	Target end date: 8-31-2013	C.2 Tailoring CM based on patient characteristics
Zwarenstein, 2011[22]	To describe the effect of CM on patient outcomes	Systematic review Including RCTs, controlled before and after and interrupted time series	All patients as long as diagnosis is not principally one of mental illness	No information located	D.3 Link components and outcomes (for different models of CM)

Note: CM=case management; COPD=chronic obstructive pulmonary disease; RCT=randomized controlled trial.

Appendix G References

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